

MALARIA AND TUBERCULOSIS IN AFRICA

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MALARIA AND TUBERCULOSIS IN AFRICA

TUESDAY, SEPTEMBER 14, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA,
COMMITTEE ON INTERNATIONAL RELATIONS,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:05 p.m. in room 2200, Rayburn House Office Building, Hon. Edward R. Royce (Chairman of the Subcommittee) presiding.

Mr. ROYCE. This hearing of the Subcommittee on Africa will come to order. The subject of this hearing is malaria and tuberculosis in Africa.

Infectious diseases cut short tens of millions of African lives every year. This is a humanitarian crisis, and these infectious diseases also weigh down Africa's economic development, it cuts the workforce productivity, it diverts public spending, and it deters desperately needed foreign investment as a result. One report suggests that malaria alone slows economic growth in African countries by 1.3 percent each year.

The United States has a strong interest in aggressively tackling infectious diseases on the continent of Africa. The United States and the international community have been focused on HIV/AIDS, and rightly so. This epidemic has taken countless lives and its death toll is mounting in Africa at a frightening pace. Several Subcommittee Members have been very involved in substantially increasing our response to HIV/AIDS.

Today the Subcommittee will look at malaria and tuberculosis. Former South African President Nelson Mandela, who contacted TB while imprisoned in the late 1980s, recently said:

"We cannot win the battle against AIDS if we do not also fight TB. TB is too often a death sentence for people with AIDS."

Malaria inflicts hundreds of millions of Africans and is the leading killer—the leading killer—of African children under the age of 5. Malaria increases children's vulnerability to other diseases, and it retards their physical and cognitive development. I would be remiss if I did not mention our many Government personnel who serve in Africa and confront malaria daily. In my travels throughout the continent, I have met many State Department and AID personnel who have suffered from malaria, in some instances, quite severe cases of malaria.

All of us should be concerned that malaria and TB are spreading despite international commitments. In 1998, the World Health Organization and other agencies committed to cut malaria deaths in

half by 2010. Yet too few Africans today are receiving aid to ward off malaria, or effective care when the disease is contracted. For many reasons, malaria deaths, instead of decreasing toward that goal, are actually on the uptick, they are increasing in Africa. TB infections are rising in Africa, largely tracking the spread of HIV/AIDS. That is the bottom line. We need to constantly question our efforts, especially when the diseases we are attacking are rising.

When considering strategies to fight malaria, we must consider the efficacy, operational feasibility and cost-effectiveness of each possible option, whether it be providing insecticide-treated netting, providing medicine, or pesticides to protect homes or other methods. In deciding the best mix for all infectious diseases, sound science must be the guide, with politics left behind. The stakes are too high for us to be anything but resourceful, open-minded and aggressive in helping Africans contend with infectious diseases. I am encouraged to see that the Global Fund, in response to outside pressure, is beginning to provide ACT and other drugs of higher effectiveness.

The international community alone cannot solve Africa's health problems. While we all need to do more, it is Africa's leaders who bear the greatest responsibility in this. I read a recent article on Equatorial Guinea, whose Government is squandering tens of millions of dollars, if not more, as its leadership enriches itself with newly-generated oil revenues. In Equatorial Guinea, where malaria is rampant, the Government is spending 1 percent—1 percent—of its revenues on health. That is immoral. This is an extreme example, but African leaders as a whole must do better. They must answer the call that the former President Nelson Mandela is putting to us to do more.

[The prepared statement of Mr. Royce follows:]

PREPARED STATEMENT OF THE HONORABLE EDWARD R. ROYCE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA

WASHINGTON, D.C.—The following is the opening statement of Africa Subcommittee Chairman Ed Royce (R-CA-40) at today's hearing examining malaria and tuberculosis in Africa:

"Infectious diseases cut short tens of millions of African lives each year. This is a humanitarian crisis. They also weigh down Africa's economic development, cutting workforce productivity, diverting public spending, and deterring desperately needed foreign investment. One report suggests that malaria alone slows economic growth in African countries by 1.3 percent per year. The U.S. has a strong interest in aggressively tackling infectious diseases on the continent.

"The U.S. and the international community have been focused on HIV/AIDS. And rightly so. This epidemic has taken countless lives, and its death toll is mounting at a frightening pace. Several Subcommittee members have been very involved in substantially increasing our response to HIV/AIDS.

"Today, the Subcommittee will look at malaria and tuberculosis (TB). Former South African president Nelson Mandela, who contracted TB while imprisoned in the late 1980s, recently said ' . . . we cannot win the battle against AIDS if we do not also fight TB. TB is too often a death sentence for people with AIDS.' Malaria inflicts hundreds of millions of Africans, and is the leading killer of African children under the age of five. Malaria increases children's vulnerability to other diseases and retards their physical and cognitive development. I would be remiss if I didn't mention our many government personnel who serve in Africa and confront malaria daily. In my travels throughout the continent I've met many State Department and AID personnel who have suffered from malaria, in some cases, quite severe cases.

"All of us should be concerned that malaria and TB are spreading, despite international commitments. In 1998, the World Health Organization and other agencies committed to cut malaria deaths in half by 2010. Yet too few Africans today are re-

ceiving aid to ward off malaria, or effective care when the disease is contacted. For many reasons, malaria deaths, instead of decreasing toward that goal, are increasing in Africa. TB infections are rising in Africa, largely tracking the spread of HIV/AIDS. That's the bottom line. We need to constantly question our efforts, especially when the diseases we're attacking are rising.

"When considering strategies to fight malaria, we must consider the efficacy, operational feasibility, and cost effectiveness of each possible option, whether it be providing insecticide-treated netting, medicine, pesticides to protect homes, or other methods. In deciding the best mix for all infectious diseases, sound science must be the guide, with politics left behind. The stakes are too high for us to be anything but resourceful, open-minded and aggressive in helping Africans contend with infectious diseases. I'm encouraged to see that the Global Fund, in response to outside pressure, is beginning to provide ACT and other drugs of higher effectiveness.

"The international community alone can't solve Africa's health problems. While we all need to do more, it is Africa's leaders who bear the greatest responsibility. I read a recent article on Equatorial Guinea, whose government is squandering tens of millions of dollars, if not more, as its leadership enriches itself with newly generated oil revenues. In Equatorial Guinea, where malaria is rampant, the government is spending one percent of its revenues on health. One percent. That's immoral. This is an extreme example, but African leaders as a whole must do better."

Mr. ROYCE. I will now turn to the Ranking Member, Mr. Payne, for an opening statement.

Mr. PAYNE. Thank you very much, Mr. Chairman, and thank you for calling this very important hearing on malaria and tuberculosis in Africa. It is very timely and I would like to certainly associate myself with your remarks.

The statistics on HIV/AIDS in Africa, certainly, are gaining increasing attention over the last few years and it is good that we are finally focusing on the problem.

The work of the AIDS activists, NGO experts, health practitioners and people working in this field finally paid off when January 28, 2003, in the State of the Union Address, President Bush announced his \$15 billion initiative to fight HIV and AIDS in Africa and the Caribbean, known as the President's Emergency Plan for AIDS Relief (PEPFAR).

I also have to commend our colleagues in Congress who have worked tirelessly to fight HIV and AIDS, including Barbara Lee, who is a Member of this Subcommittee and has made this a number one passion of hers.

The PEPFAR initiative was a welcome shift of attention to the growing pandemic which claimed the lives of approximately 2.4 million Africans in the year 2003 alone. Since the President's initial announcement, there have been concerns about providing the resources the initiative calls for. Others, including myself, have called for a more multilateral approach through greater funding to the Global Fund to Fight AIDS, TB and Malaria.

This brings me to the point of this hearing: It is critically important that we broaden our focus in the fight against HIV/AIDS and understand the dangerous nexus between HIV, TB and malaria. More than 29 million people in sub-Saharan Africa are currently living with HIV and AIDS. Malaria and HIV together kill more than 4 million people each year, approximately 90 percent of which are in Africa. But malaria is still the leading cause of child mortality under the age of 5.

We have not effectively dealt with malaria and are now witnessing the devastating impact of malaria and HIV working in an overlapping way, both geographically speaking and in terms of the causal relationship. According to the World Health Organization

report of June 2004, in nonpregnant women and adult men, HIV/AIDS may increase the risk of malaria, and we know because it weakens the immune system.

By the same token, severe cases of malaria can increase HIV viral load. In HIV-infected pregnant women, malaria is more likely to develop. And this is a serious cause of concern because when mothers die, children under 5 have less of a chance of survival. It also compounds the already serious orphan problem, which sometime we really have to spend an entire hearing on, and which is extremely devastating.

The World Health Organization report calls for high priority for people living with AIDS in high-malaria-transmission areas to be protected by insecticide-treated nets, as we have already heard the Chairman mention, particularly HIV-positive pregnant women. It also calls for an integrated approach to treatment, as well as more research on interaction of anti-retroviral and anti-malaria drugs.

The point that I would like us to take a look at in the hearing is that ending malaria is something very doable. As a matter of fact, if malaria was in the G-8 countries, there would have been a cure for it many, many decades ago. But many of the pharmaceutical companies felt that if they did concentrate, spend tons of money, have the medicines to deal with it, then who is going to pay for it? So other, more economically-supportive diseases took a higher priority.

There is no question that malaria kills, has been killing, probably has killed more people in the world than any other disease, but there has never been a concentrated approach by the world pharmaceutical industries to deal with it. Hopefully we can get more attention to it with some of the new opportunities.

There is no reason why in 2004 women should be dying in childbirth and more than 3,000 children should die in Africa each day from malaria. That is one African child dying every 30 seconds and it is only getting worse.

We need to support the Roll Back Malaria Campaign, which was launched in 1998 to cut malaria in half globally by the year 2010. The founding partners are WMDP, UNICEF, the World Bank and WHO. So far, \$200 million a year is spent on malaria but there is certainly more that can be done.

The other forgotten killer that we are here to talk about is tuberculosis. TB is on the rise, yet it is not talked about enough. We need more to be said about the deadly relationship that exists between TB and HIV/AIDS, often called the twin epidemic. Twelve million people worldwide are infected with both HIV/AIDS and tuberculosis. Killing one-out-of-three people infected with AIDS, tuberculosis is now the leading cause of death in people HIV positive.

Let me conclude by saying we need to take a serious look at our efforts to fight HIV/AIDS, malaria and tuberculosis, and ask ourselves if what we are doing is adequate. Clearly we cannot have a single-minded approach to any of these three killers and must instead integrate our response. Joint treatments are a must.

Malaria, TB and HIV/AIDS are diseases that are caused, as well, by poverty, and until we really start dealing with poverty elimination, we are going to continue to have these diseases that follow poverty. We cannot be serious about development without effec-

tively dealing with these three major diseases. The people of Africa deserve to have hope for a brighter, healthier future, just as much as any American, European or Asian does. These are global problems that warrant a global collaborative approach.

Once again, Mr. Chairman, thank you for your patience on this extra-long opening statement, but it is so important that I appreciate your indulgence.

[The prepared statement of Mr. Payne follows:]

PREPARED STATEMENT OF THE HONORABLE DONALD M. PAYNE, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. Chairman, I'd like to thank you for calling this very important hearing today on Malaria and Tuberculosis in Africa.

The statistics on HIV/AIDS in Africa have certainly gained increasing attention over the last few years. The work of AIDS activists, NGO experts, health practitioners, and people living with AIDS finally paid off when in his January 28, 2003 State of the Union Address, President Bush announced his \$15 billion initiative to fight HIV/AIDS in Africa and the Caribbean, known as the President's Emergency Plan for AIDS Relief (PEPFAR).

I also have to commend our colleagues in the Congress who have worked tirelessly to fight HIV/AIDS, including Barbara Lee on this subcommittee.

The PEPFAR initiative was a welcome shift of attention to the growing pandemic which claimed the lives of approximately 2.4 million Africans in the year 2003 alone.

Since the President's initial announcement, there have been concerns about providing the resources the initiative calls for. Others, including myself, have called for a more multilateral approach through greater funding to the Global Fund to fight AIDS, TB, and Malaria.

This brings me to the point of this hearing: it is critically important that we broaden our focus in the fight against HIV/AIDS and understand the dangerous nexus between HIV, TB, and Malaria.

More than 29 million people in Sub-Saharan Africa are currently living with HIV/AIDS. Malaria and HIV together kill more than 4 million people each year, approximately 90% of which are in Africa. But malaria is still the leading cause of child mortality under the age of 5. We have not effectively dealt with malaria and are now witnessing the devastating impact of malaria and HIV working in an overlapping way both geographically speaking and in terms of the causal relationship.

According to a World Health Organization report in June of 2004, in non-pregnant women and adult men, HIV/AIDS may increase the risk of malaria. By the same token, severe cases of malaria can increase HIV viral load. In HIV-infected pregnant women, malaria is more likely to develop and this is a serious cause of concern because when mothers die, children under 5 have less of a chance of survival. It also compounds the already serious orphan crisis on the continent.

The WHO report calls for high priority for people living with AIDS in high malaria transmission areas to be protected by insecticide-treated nets, particularly HIV-positive pregnant women. It also calls for an integrated approach to treatment as well as more research on the interaction of antiretrovirals and anti-malarial drugs.

The point that I would like us to take from this hearing is that ending malaria is something very doable. There is no reason why in 2004 women should be dying in childbirth and more than 3,000 children should die each day in Africa from malaria. That's one African child dying every 30 seconds. And it is only getting worse.

We need to support the Roll Back Malaria Campaign which was launched in 1998 to cut malaria in half globally by 2010. (The founding partners are UNDP, UNICEF, The World Bank, WHO). So far \$200 million a year is spent on malaria but there is certainly more than can be done.

The other forgotten killer that we are here to talk about is Tuberculosis. TB is on the rise, yet it is not talked about enough. More needs to be said about the deadly relationship that exists between TB and HIV—often called the "twin epidemic". 12 million people worldwide are co-infected with both HIV and TB. Killing 1 out of 3 people living with AIDS, TB is now the leading cause of death in people who are HIV positive.

We need to take a serious look at our efforts to fight HIV, Malaria, and TB and ask ourselves if what we're doing is adequate. Clearly, we cannot have a single-

minded approach to any of these 3 killers and must instead integrate our response. Joint treatments are a must.

Malaria, TB, and HIV are diseases of as well as causes of poverty. We cannot be serious about development without effectively dealing with these 3 major diseases. The people of Africa deserve to have hope for a brighter, healthier future just as much as any American, European, or Asian does. These are global problems that warrant a global collaborative approach.

I thank you again Mr. Chairman and look forward to the witness testimonies.

Mr. ROYCE. I would like to put any other opening statements in the record without objection and go to our first witness, Dr. Anne Peterson.

Dr. Peterson, your report, which we have read, is 17 pages. We are going to have to urge you to keep within the confines of 5 minutes, and that will give us time to go through some questions that we want to ask you.

Dr. Anne Peterson is the Assistant Administrator of the Bureau for Global Health, U.S. Agency for International Development. Before taking on this position, she worked for 3 years as Commissioner of Health for the State of Virginia.

Dr. Peterson has an extensive background in both U.S. and international public health and medical practice. She is the author of numerous publications and spent 6 years in sub-Saharan Africa promoting public health and conducting research.

Thank you, Dr. Peterson, for coming before this Subcommittee. We appreciate the opportunity to hear from you.

STATEMENT OF THE HONORABLE E. ANNE PETERSON, ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Dr. PETERSON. Thank you, Chairman Royce and Congressman Payne, for both convening this hearing on a very important topic of malaria and TB. I do promise my enthusiasm will not go to 17 pages.

But these are diseases, as you said, that affect the health and wealth of nations and individuals and especially in Africa. I am a public health physician who has lived and worked both internationally and domestically, and it is really wonderful for me to finally see attention being brought to bear on malaria and TB, as well as HIV.

Worldwide, malaria does have the greatest burden of disease, with 500 million persons affected annually compared to 5.3 million for AIDS and 8.8 million for TB, and does lead to approximately \$12 billion a year loss in gross domestic product in Africa alone. It is estimated that malaria kills more than 1 million people—that is third after AIDS and TB—and that 90 percent of those deaths are, again, in Africa. As many as a quarter of the childhood deaths in endemic areas are due to malaria, and infection in women takes a huge toll, both on the mother and on the newborns.

I thank Congressman Payne, especially, for raising the new studies and information about the susceptibility of people who are HIV positive to increased rates of disease and death due to malaria. This is a newly identified and vulnerable population in an area that is growing very rapidly.

Malaria can be insidious or dramatic and I personally have experienced both. My husband and I lived for 4 years in Africa. My chil-

dren grew up there. My youngest was born in Kenya with all the inherent risks of having a pregnancy in Africa, and my husband almost died of malaria. After failing treatment with chloroquine and the next line drugs, he ended up in the hospital on IVs with drug-resistant malaria. This is an issue I care very deeply about.

The United States is, and has been, a leading force in the worldwide battle against malaria. We have committed more than \$80 million for malaria programs just this year. That is nearly a four-fold increase since 1998 when the initiative was launched. Again, we thank you for that increased funding.

The missions at USAID provide programs in 20 countries in sub-Saharan Africa where the burden of malaria is the highest. International experts have identified three priority interventions that have been proven to reduce death and illness from malaria in an integrated program. They are provision of prompt and effective treatment, prevention of malaria through insecticide-treated nets, and provision of intermittent preventive treatment for pregnant women. Other parts of the integrated program, depending on the country and the mosquito factor, are indoor residual spraying, the use of insecticides, and environmental cleanup.

USAID has been very concerned about the increase in malaria and has invested significant resources into documenting the speed and the scope of developing anti-malarial drug resistance and the increasing number of deaths. We know from many infectious diseases that simultaneous use of multiple drugs instead of a single regimen slows development to resistance. And the World Health Organization, Roll Back Malaria, including USAID, now recommends that all countries experiencing resistance to their current first-line, single-therapy drug should change to a combination therapy, ideally including artemisinin drugs, the ACTs.

USAID has played a key role in supporting changes to national malaria treatment policy to ACTs for three of the six countries in the Mekong region, and six to eight countries making up the Amazon Basin, and for six countries in Africa.

USAID and our global partners have been working in endemic countries to assess the treatment needs, working with pharmaceutical producers to gauge their interest, willingness and ability to scale-up the production of ACTs. We have been working with financial institutions, like the Global Fund and the World Bank, to look at financing for ACTs, and with the development and technical agencies to ensure in-country implementation once we have all of those resources.

The most recent forecast from RBM for 2005 projects the need for 125- to 150-million treatments of ACTs for Africa, a nearly five-fold increase over 2003 production levels, and by 2008 we will need more than 300 million treatments.

USAID and its partners in Roll Back Malaria are negotiating with agricultural producers in Africa to encourage the farmers to cultivate more plants containing artemisinin, the core substance within the ACTs. We hope and expect this Global Development Alliance, a public-private partnership, will be able to produce enough of the active pharmaceutical ingredient to triple the drug availability by 2005 in order to meet the needed 150 million doses.

For malaria prevention, consistent use of insecticide-treated nets has been shown to decrease malaria deaths and cases. We have had recent articles, as recently as August 2004, showing that it is as effective a malaria control intervention as house spraying with DDT, and that the role of bed nets and other interventions permitted reduced use of DDT spraying for any given target incidence.

We know that nets can be deployed in desperately poor countries where the deaths are the highest and that this puts into the hands of parents the ability to protect their children, rather than relying on outside Government programs. USAID does provide free nets and promotes targeting free and heavily-subsidized nets to the poorest and the most vulnerable: Pregnant women, children under 5, and HIV-positive persons based on recent policy changes.

We work with the NetMar partnership to bring in the commercial sector to expand our ITN market and are already seeing promise that this partnership will be able to avert almost 1 million deaths.

Contrary to popular belief, USAID does support the use of DDT in malaria control programs. We promote careful use of DDT for malaria control through the spraying of interior house walls, the indoor residual spraying, or IRS.

Last December I visited Ethiopia as they were responding to an unprecedented wave of malaria deaths. We were supporting Save the Children which was using both the nets and the indoor residual spraying. But IRS does require an infrastructure. It requires large teams of personnel in countries that often, as the discussions on AIDS has shown, have limited human capacity.

We have, as was mentioned earlier, the Global Fund, where significant resources are going to AIDS, TB and malaria. USAID is on the board of the Global Fund, and we also are on the technical review panels, and we work with our in-country missions to make sure that there are programs for all three diseases that are going to be able to be implemented well.

Private-sector work, again, leverages our scarce dollars in partnerships with private-sector companies to bring a greater amount of net production and drug availability. As we consider the plight of those who face disease, we are looking at as many partnerships as we can and as much leveraging of our resources as we can.

For tuberculosis, I will just say that very similarly we are tracking the disease, we are working to bring new drugs to the market, we are involved in the Stop TB global partnerships where USAID is on the board and I am on the executive committee as well, and we are funding the Global Drug Facility (GDF) for TB drugs. One of the very important things about our work with Global Fund is to try and encourage countries to link between their Global Fund grants to the GDF, which has done a very good job of reducing TB drug prices, and making both of those alliances stronger.

In India we are working with community providers. And I have just been to Russia with Secretary Thompson where we were looking at multidrug-resistant TB, especially in the prison situation, and seeing a real resurgence of not only the problem, but finally some political will to address those.

So in TB, similarly to malaria, there is not a single drug answer; there is not a single bullet for either treatment or prevention. We

are very pleased to be able to be working on both of these problems.

Thank you.

Mr. ROYCE. Thank you very much, Dr. Peterson.

[The prepared statement of Dr. Peterson follows:]

PREPARED STATEMENT OF THE HONORABLE E. ANNE PETERSON, ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Thank you, Chairman Royce and Congressman Payne, for convening this important hearing and for inviting me to testify. Thank you for spotlighting these two very deadly diseases, malaria and tuberculosis (TB). They affect the health and wealth of nations and individuals alike around the world, but especially in Africa. They are not only diseases of poverty but also diseases that cause poverty and are major constraints to economic development.

As a public health physician who has worked internationally and domestically for more than 20 years, I am very pleased at the growing interest and response to the challenge these epidemics pose. The international community has mobilized funding and action recently to develop and implement sustainable actions against both malaria and TB. I will first address the burden and suffering caused by malaria and outline what USAID is doing to save lives now and in the future and then I will do the same for TB.

Malaria

Worldwide, it is estimated that malaria kills more than one million people each year, making it the world's third deadliest infectious disease, after AIDS and tuberculosis. But malaria—spread by mosquitoes—is the most common of the three diseases, with more than 500 million persons experiencing acute malaria illness annually, compared with 5.3 million for AIDS and 8.8 million for TB. Malaria also accounts for a loss of approximately \$12 billion a year in gross domestic product in Africa alone.

Ninety percent of malaria deaths occur in Africa. Malaria's greatest impact is felt by very young children in Africa and pregnant women because of their reduced immunity to the malaria parasite. As many as a quarter of childhood deaths in endemic areas are attributable to malaria. But infection of women during pregnancy also takes a huge toll, both on the health of the mother as well as on the development of her unborn child. Placental infection is a significant contributor to low birthweight and subsequent neonatal death. In areas of unstable or epidemic malaria, all persons are at risk of serious illness and death. The drain on the physical and financial resources of households and communities of the disease, as well as the often ineffective attempts to respond to it, is well documented. With burgeoning AIDS epidemics in malarious countries, the risk of death due to malaria increases dramatically in a new vulnerable population.

Scope of USAID role in battling Malaria

The United States is and has been a leading force worldwide in the battle against malaria. USAID has directed and supported critical research that forms the backbone of some of the most effective interventions, including insecticide-treated mosquito nets (ITNs) and drugs. It is also studying ways to identify and deal with increasing drug resistance. Our technical and financial resources are being brought to bear around the world and leveraged to increase global commitments to reduce death. This year USAID committed just over \$80 million for malaria programs—a nearly four-fold increase since 1998 when USAID's Infectious Disease Initiative was launched. These new and expanded resources have allowed for a significant scaling-up of malaria activities from 5 countries to 20 now targeting national level impact and leading to increased coverage with interventions, better policies and visibly stronger programs.

USAID missions provide support to national malaria control programs in 20 countries in sub-Saharan Africa, where the burden of malaria deaths is the highest. This support covers a broad range of activities. These are determined by local priorities, resource availability, and complementary activities by other donors and multinational institutions.

The international efforts to fight malaria are largely coordinated by a global partnership that includes leaders from across Africa, African health institutions, the World Health Organization (WHO), UNICEF, World Bank, UNDP, multi-lateral agencies, the Centers for Disease Control and Prevention (CDC), international, na-

tional and local NGOs, and the private sector. USAID is a key partner in the Roll Back Malaria Partnership.

Integrated Flexible Program Approach Saves Most Lives

International experts have identified three priority interventions to reduce deaths and illness from malaria, each of which is backed by solid evidence of their effectiveness. These three interventions are consistent with USAID's priority areas for investment in malaria. They are:

1. Provision of prompt and effective treatment with an antimalarial drug within 24 hours of onset of fever; and
2. Prevention of malaria primarily through the use of insecticide-treated mosquito nets (ITNs) by young children and pregnant women;
3. Provision of intermittent preventive treatment (IPT) for pregnant women as a part of the standard antenatal services—proper use of which can reduce overall child deaths by up to 30% and significantly reduce sickness in children and pregnant women.

Other parts of an integrated program include as appropriate epidemiology and based on mosquito characteristics are:

- a. Indoor Residual Spraying and use of insecticides
- b. Environmental Clean-up to remove mosquito breeding sites

The three interventions to reduce deaths and illness from malaria are internationally agreed upon, especially for Africa where the Abuja Targets are set at exceeding 60% coverage for each.

Improving Treatment with Effective Drugs

Historically, national malaria control programs have relied primarily on monotherapy with drugs, such as chloroquine, amodiaquine, or sulfadoxine-pyrimethamine (Fansidar®). These are the first-line treatment for *Plasmodium falciparum* infections, which are responsible for the vast majority of deaths due to malaria.

USAID Instrumental In Tracking Spread Of Resistance—Documenting Need For Better Drugs

Like many infectious diseases, even with extensive resources and attention, resistance to drugs can develop and the disease can escalate, as we are seeing in the development of multi-drug resistant TB. The spread and intensification of antimalarial drug resistance has risen greatly over the past 20 years. In Southeast Asia, strains of *P. falciparum* have developed resistance to multiple antimalarial agents and very few drugs remain effective. In South America, high levels of resistance to both chloroquine and Fansidar are already present throughout the Amazon Basin. In Africa south of the Sahara, where the impact of *P. falciparum* infections in pregnant women and children under five is greatest, chloroquine resistance is now widespread and there is increasing resistance to Fansidar in East and southern Africa.

Drug Resistant Strains Set Additional hurdles

USAID has been instrumental in trying to measure the speed and scope of developing antimalarial drug resistance. As drug resistance increases, the choice of first- and second-line drugs for malaria treatment has become much more difficult. Only a limited number of alternative drugs are available and there is little economic incentive for new drug discovery and development, given its high cost and the fact that malaria predominantly affects the world's poorest nations. Furthermore, in many malarious areas, a majority of the population does not have ready access to malaria treatment and those drugs that are available may be of substandard quality.

Investing in Increased Surveillance to Detect Epidemics

The ability to control infectious diseases requires effective comprehensive surveillance and response capacity. Effective surveillance is a prerequisite for:

- establishing local, national, regional, and global priorities; for planning, mobilizing, and allocating resources;
- for detecting epidemics in their early stages; and
- for monitoring and evaluating disease prevention and control programs.

The Agency's Disease Surveillance Program stresses the development of a strong local and national foundation for collecting, analyzing and using public health infor-

mation. USAID is contributing to the development of this foundation through technical assistance and participation in regional and global initiatives.

USAID invests more than \$7 million each year to strengthen routine monitoring for emergence and spread of drug resistant malaria and reporting of diseases, enabling governments to quickly identify and respond to a malaria outbreak in a region.

Mainstreaming Rapid Diagnostics

New community-based approaches to diagnostics, including rapid diagnostics tests, can help overcome insufficient laboratory capacity or resource shortages to enhance from receiving disease surveillance information to response. USAID is working to develop diagnostics tests for both *falciparum* and *Vivax* infections, assisting in manufacturing and mainstreaming the use of rapid diagnostic kits around the world. In South East Asia, ACTs are routinely deployed with rapid diagnostic test kits, and in Africa, these tests are rapidly becoming integral in process of malaria diagnosis.

Identifying Drug Resistance Factors

Improper prescription of medications by pharmacists and self-prescribing of malaria medications contribute to malaria drug resistance. Poor quality and counterfeit malaria medications also contribute to drug resistance as well as ill health and death. In an effort to improve prescription practices and assure effective malaria medications reach consumers, USAID supported research studies in Africa, Asia and Latin America to determine the extent of improper malaria medication practices. They found that household treatment practices are all too often inadequate. In Cambodia, for instance, it was found that only 11 percent of people with symptoms of malaria received the nationally recommended first-line therapy. Moreover, 41 percent of people receiving treatment for malaria did not take the full course of the malaria medications. And 50 percent of people were self-prescribing with medications obtained in the private market.

Ensuring Drug Quality

USAID is strengthening national drug regulatory authorities. The aim is to improve the manufacturing of pharmaceuticals through good manufacturing practices, including drug quality control in national malaria programs. At 17 sentinel surveillance sites in six countries in Southeast Asia and Africa, antimalarial drugs are collected and tested for quality, using low technology screening methods. Sentinel surveillance sites and malarial control programs will be linked to create regional warning systems for poor quality drugs found in the market. A new collaborative effort is underway as part of the US-Japan common agenda to provide laboratory equipment to backup this surveillance effort. The United States Pharmacopeia Drug Quality and Information program (USP DQI) has also provided technical assistance in good manufacturing practices to selected producers of malaria drugs in Cambodia, China, Laos, and Vietnam.

Combination Therapy Recommended by WHO, Roll Back Malaria and USAID

We know from many infectious diseases that simultaneous use of multiple drugs instead of a single regimen slows development of resistance. The World Health Organization (WHO) and the Roll Back Malaria partnership (including USAID as one of the partners) now recommend that all countries experiencing resistance to their current first-line, single-drug therapy should change to a combination therapy, ideally including an artemisinin drug. The rationale for using combination therapy for malaria is similar to that for the treatment of tuberculosis, cancer, and HIV infections. When used alone, antimalarial drugs are more likely to select resistant parasites. The addition of a rapidly-acting and highly effective second drug, such as artemisinin or one of its derivatives, greatly reduces the probability of selecting parasites that are resistant to both drugs. This should prolong their useful therapeutic lifetimes. The WHO and Roll Back Malaria (RBM) recommend several artemisinin-based combination therapy (ACT) options: artemether/lumefantrine (Coartem®) or artesunate plus either amodiaquine, sulfadoxine-pyrimethamine, or mefloquine. USAID has supported the development and critical research for ACTs.

Over the past year the RBM partnership has developed a comprehensive "roadmap" on how best to ensure access to and effective use of ACTs. The roadmap highlights major milestones and potential barriers towards achieving full access to and appropriate use of ACTs—and more importantly, establishes a framework for prioritizing the actions of the RBM partnership. The most recent forecasts by RBM's Malaria Medicine and Supplies Services unit for 2005 project a need of between 125–150 million treatments of ACTs in Africa. This represents a nearly five-fold increase over 2003 world-wide ACT production levels and projects a need in excess of 300 million treatments annually by 2008.

USAID and our global partners have worked with endemic countries over the past several months to assess their treatment needs. We are working with pharmaceutical producers to gauge their interest, willingness, and ability to scale-up production of ACT as well as with financial institutions to determine their ability to mobilize sufficient support for the financing of ACTs. We are also seeking help from development and technical support agencies to ensure in-country support for effective application of these resources.

We have identified four potential “bottlenecks” or barriers that hinder access to and effective use of ACTs

- The capacity of agricultural producers to increase their yields of the plant *Artemisia annua*, the source of artemisinin
- The number and capacity of pharmaceutical industry to produce high quality ACTs
- The availability of resources to finance their procurement
- The availability of training and capacity to build support in country for widespread use.

The identification of these potential bottlenecks in turn has led to an agreement within the RBM partnership of the key actions needed for their resolution.

Product Availability: Overcoming Obstacles to Scaling Up ACT

USAID and its partners in Roll Back Malaria are currently negotiating with agricultural producers in Africa to encourage farmers to cultivate more artemisinin-based drugs. Funding from the Global Development Alliance is seeking production of enough of the active pharmaceutical ingredient to triple the drug availability in 2005 to a total 150 million doses.

Enhancing Production Quality and Capacity

Ensuring high quality and low cost ACTs requires an adequate pool of qualified ACT producers. Currently, there are only three pharmaceutical companies which have been “prequalified” by WHO as manufacturers of quality ACTs. USAID in 2004 and 2005 will continue to work with WHO to maximize the number of “prequalified” companies. USAID’s support will target both upgrading the production capacity of pharmaceutical companies to meet WHO’s standards for prequalification and will assist the WHO in expediting the evaluation process.

Financing ACTs

Financing ACTs poses substantial challenges. An additional \$30–\$60 million will be required to finance ACTs in 2004. This amounts to between \$200 and \$300 million annually by 2006. Towards meeting the forecasted production and 2007 financing “gap” USAID and RBM partnership is taking a two-pronged strategy: (1) to identify and ensure adequate financing over the next 18–24 months for country procurement of ACTs; and (2) to address the longer-term financing of ACTs. To meet the long-term demand, USAID has commissioned the Institute of Medicine to convene an expert panel to study options for funding ACTs from 2007 and beyond. This study has just been released and provides a clear and practical “roadmap” for the long-term financing of ACTs.

While recent public discussions of malaria treatment have largely focused on which drugs to use, the real challenge to providing effective treatment is in the “nuts and bolts” of delivering these drugs to those in need: enabling policies must be in place; logistic and management capabilities need to be upgraded; health workers need to be appropriately trained and supported; and community and household practices need to be knowledgeable and cognizant of appropriate services. USAID is working with partners in the public and private sector in all of these areas to ensure that effective and safe antimalarial drugs get to the patients who need them.

With these and other similar challenges in mind, USAID is bringing the full weight of its technical and programmatic resources in support of those countries that have made changes in their policies to ACTs to ensure that they have adequate support in procurement and management of ACTs, training of health workers in diagnosis and use of ACTs for treatment of malaria, and mobilizing communities and households. USAID is also presently working with 25 Global Fund recipient countries in preparing detailed plans for the introduction of ACT over the next year.

Prevention of Malaria

For those individuals at risk from malaria in the highest risk areas of Africa (south of the Sahel and north of the Zambezi River), insecticide treated nets (ITNs) are the most practical and effective means for protecting the largest percentage of populations. Consistent use of an ITN has been shown to decrease severe malaria

by 45%, reduce premature births by 42% and cut all-cause child mortality by 17%–63 %. In most settings, ITNs are unquestionably the most effective way that families can protect themselves from malaria.

ITNs can be deployed now in the desperately poor countries in Africa where malaria-related mortality is highest and can be put into the hands of parents who want to protect their children. As a consequence there is a strong international consensus that ITNs, particularly in these rural African settings with a high malaria burden, are the best primary prevention intervention. This is the reason USAID has constructed a prevention program that strongly emphasizes the use of ITNs.

Free Nets To Those Most In Need

USAID promotes targeting free or heavily subsidized ITNs to the most vulnerable (pregnant women and children under five years) and poorest populations—thus ensuring economics is not a barrier to net ownership. It is important that this targeted distribution of subsidized ITNs be combined with developing systems for ensuring long-term availability of ITNs for households and communities in Africa. Thus USAID supports expanding commercial market distribution, developing new technologies—especially in the area of long-lasting ITNs, and the growing of ITN production capacity to ensure adequate supplies of affordable and quality ITNs.

USAID has developed innovative models for the delivery of highly subsidized or free ITNs in collaboration with national malaria control programs in Ghana, Senegal and Zambia, as well as UNICEF, DfID, IFRC, NGOs and private sector partners such as ExxonMobil. With UNICEF this involves delivery of subsidized ITNs linked to routine immunization; with the Red Cross, ITNs are provided at no cost as part of targeted measles campaigns, and with ExxonMobil, the nets are delivered via a heavily subsidized voucher program through antenatal clinics.

Commercial Partnership In ITNs For Those Who Can Afford To Build Sustainability

USAID supported a partnership called NetMark which is working with 13 major commercial firms (representing over 80 percent of the global capacity to produce and distribute ITNs) to share the risks of developing ITN markets, to identify and reduce barriers to effective engagement of the commercial sector, and to create demand, thereby expanding availability of affordable ITNs. This effort, joined with that of the many Roll Back Malaria partners to scale-up ITN access and use throughout Africa, can reduce malaria deaths by one million annually. This successful cooperation with the commercial sector will serve as a model in other parts of the world and with other health related products.

New technologies now provide long-lasting nets and treatments that remove the necessity for retreatment. These technical developments, the product of committed commercial sector engagement with Roll Back Malaria partners, render ITNs even more affordable, more easily used, and more effective. ITNs also have an additional advantage. Studies show some protection of children who live nearby a net, as opposed to IRS where there is no added protection.

USAID is investing in building the capacity of African distributors and their suppliers to distribute and promote ITNs on a national scale. Strategic investments are made to support companies through a matching fund scheme, while generic behavior change communication campaigns create demand on a national scale.

The World Health Organization has noted an important trend in increasing ITN use since 1998. According to the Africa Malaria Report 2003, about 15% of African children slept under mosquito nets and 2% under insecticide-treated nets. Although these rates are far from satisfactory, more recent country-specific surveys are recording higher rates, and this adoption of mosquito nets throughout Africa reflects a profound, if incipient, change in behavior and attitude. The main barriers to scale up with ITNs have been changing residents' attitudes and behavior, cost of the nets, and limited distribution systems. To overcome these barriers, USAID is supporting targeted distribution of free or highly subsidized ITNs to children under 5 and pregnant women, extensive social marketing efforts and is working closely with net manufacturers and distributors in many African countries. As a consequence of these efforts we are on a trajectory to provide more than three million ITNs in 2004. USAID anticipates that sales of ITNs in seven target countries in 2005 will at least double and could reach seven million.

Prevention of Malaria in Pregnancy

Each year, more than 30 million African women become pregnant in malaria-endemic areas and are at risk for *Plasmodium falciparum* malaria infection during pregnancy. Most women live in areas with relatively stable malaria transmission, where the major impact of infection during pregnancy is related to anemia in the mother and the presence of parasites in the placenta. The resulting impairment of fetal nutrition contributing to low birth weight (LBW) is a leading cause of poor in-

fant survival and development in Africa. HIV infection diminishes even more a pregnant woman's ability to control *P. falciparum* infections. The prevalence and intensity of malaria infection during pregnancy is higher in women who are HIV-infected. Women with HIV infection are more likely to have symptomatic infections and to have an increased risk for malaria-associated adverse birth outcomes.

WHO has recommended intermittent preventive treatment (IPT) using the antimalarial drug, sulfadoxine-pyrimethamine (SP), as the preferred approach to reduce the adverse consequences of malaria during pregnancy in areas with stable transmission. Since more than 70% of pregnant women in Africa attend antenatal clinics, IPT provides a highly effective base for programmes through use of safe and effective antimalarial drugs in treatment doses which can be linked to antenatal clinic visits. The potential of IPT to attain high levels of program coverage and its benefit in reducing maternal anemia and LBW makes it a preferred strategy in sub-Saharan Africa. In HIV-negative pregnant women, two doses of IPT provides adequate protection, but a minimum of three doses appears to be necessary in HIV positive women. Outside of areas with stable transmission in Africa and in other regions of the world, while malaria in pregnancy is a risk for both the mother and fetus, there is no evidence that IPT is worthwhile.

USAID played a key role in supporting the original studies in Africa that documented the efficacy of IPT in preventing the impact of malaria on both HIV positive and HIV negative pregnant women and their offspring. Many countries have already changed their malaria in pregnancy policies. Currently, through a coalition of partners, USAID is assisting ministries of health in about 10 African countries to implement IPT and distribute ITNs as part of a package of health interventions at the antenatal clinic level. Over the last year this technical assistance has contributed significantly to revision of outdated policies in Senegal, Ghana, Rwanda, and Zambia and to increased implementation of revised policies in DRC, Tanzania, and Kenya. Among women attending antenatal services in Tanzania, delivery of intermittent preventive therapy has increased from below 30 percent to over 60 percent.

DDT

Contrary to popular belief, USAID does not ban the use of DDT in its malaria control programs. DDT is only used for malaria control through the spraying of interior house walls—Indoor Residual Spraying, or (IRS). A number of other insecticides can also be used for IRS, and are in many countries when those alternative insecticides are safer and equally effective. IRS, when efficiently conducted in appropriate settings, is considered to be as efficacious as ITNs in controlling malaria.

From a purely technical point of view in terms of effective methods of addressing malaria, USAID and others have not seen IRS as the highest priority component of malaria programs for many reasons. In many cases, indoor residual spraying of DDT, or any other insecticide, is not practical, cost-effective and is very difficult to maintain. IRS requires major infrastructure, including a high level of organization, geographic coverage, application personnel and financial resources, regardless of what insecticide is used. To be effective, IRS needs 80 percent community compliance. It is also more expensive in rural or peri-urban than in urban areas.

In most countries in Africa where USAID provides support to malaria control programs, it has been judged more cost-effective and appropriate to put U.S. government funds into other malaria control activities than IRS. However, in countries in which circumstances support the use of IRS (including DDT), USAID has funded support to malaria control programs, for example, Eritrea, Zambia, Ethiopia and Madagascar.

USAID regulations (22 CFR 216) require an assessment of potential environmental impacts of supporting either the procurement or use of pesticides in any USAID assisted project, but if the evidence assembled in preparing such an environmental review indicates that DDT is the only effective alternative and it could be used safely (such as in interior wall spraying undertaken with WHO application protocols), then that option would be considered. The U.S. government is signatory to the Stockholm Convention on Persistent Organic Pollutants (the POPs treaty), which specifically allows an exemption for countries to use DDT for public health use in vector control programs, as long as WHO guidelines are followed and until a safer and equally effective alternative is found.

The United States voted in favor of this exemption. For example, this exemption was used to spray DDT and other insecticides in South Africa when certain mosquitoes developed resistance to the major alternative class of insecticides, the synthetic pyrethroids. Such situations are relatively rare, however, and demonstrate the value of the provisions of the POPs Treaty, which restrict and document use of DDT, but provide for its use when appropriate.

Expanding Global Network

Multilaterals, bilaterals . . . no one agency can do it all. Roll Back Malaria partners—leaders from across Africa, African health institutions, WHO, UNICEF, World Bank, bi-lateral agencies, international, national and local NGOs, and the private sector are engaged to in the fight against malaria.

Global Fund

Through the Global Fund to Fight AIDS, Tuberculosis, and Malaria, USAID and international partners have come together to combine financial, technical, management, and other expertise to reduce the public health impact of malaria. Over the past three years, the U.S. government has contributed \$623 million to the Global Fund, and has appropriated up to \$547 million this year. USAID is presently working with 25 Global Fund recipient countries to prepare detailed plans for the introduction of ACT over the next year.

We have some of the best malaria experts in the world who have been requested to be on technical review panels for the Global Fund for malaria and USAID provides in country technical assistance to assist on Global Fund proposals. Strategically, there is a rapidly evolving partnership between the Global Fund and USAID's malaria program. With USAID providing critical technical "know how" and the Global Fund providing the resources for the procurement of key commodities for the prevention and control of malaria there is a growing optimism that malaria endemic countries can soon begin turning the tide against malaria.

Private Sector

We have developed strong partnerships with many companies like Siam Dutch and A-Z in Tanzania, bringing in private dollar side by side to support public programs, leading to a 50 percent reduction in the cost of nets in the last three years. Netmark alone contributes about 55 cents to every dollar from USAID and this does not include the cost of textile (net) production. USAID is committed to reaching out beyond our traditional partners to find able and creative organizations, particularly those that are faith-based and community-based.

These actors are playing unique roles—roles only they can perform due to their expertise, positions and responsibilities.

Research institutions and pharmaceutical companies can develop improved treatments and interventions to help protect us against malaria and its impacts. USAID works closely with the CDC, which, with USAID support, provides technical assistance to the World Health Organization and ministries of health in a variety of areas related to malaria diagnosis and treatment, prevention of malaria in pregnancy, use of insecticide-treated mosquito nets (ITNs), indoor residual spraying (IRS), and monitoring and evaluation of malaria programs. USAID also provides funding to NIH for work on a malaria vaccine.

Community- and faith-based organizations and other NGOs extend deeply into many of the most rural areas, reaching societies and cultures to ensure health care services and malaria treatments and interventions get to hard-to-reach populations.

National governments have especially important roles to play with specific, attainable steps to reducing the impacts of malaria—steps that only they can take. The international donor community, in partnership with developing country partners, can ensure that technical and financial resources are allocated where they will be most effective.

USAID is committed to working with these important partners to turn the tide against malaria and other infectious diseases.

And with so many new partners, the coordination of our efforts becomes even more critical. This is as true among the U.S. government agencies as it is among our international partners, including the new Global Fund. Coordination efforts must occur at two levels: at headquarters and in the countries we are assisting.

Research

USAID has also targeted the creation of a vaccine for malaria. A vaccine candidate against malaria is currently being tested in Kenya and Mali where the disease disables or kills hundreds of thousands of people each year.

After initial safety trials in the United States, clinical trials jointly supported by the Gates Foundation, the Malaria Vaccine Initiative began last year in Kenya with a safety study on some 50 adults.

The tests showed that the vaccine was safe in adults in Kenya, so this year testing was extended to about 50 children aged 1 to 4 years. The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), is now working with USAID in testing the vaccine on some 40 adults in Mali to obtain safety data in a different epidemiological setting.

While ACTs are now effective, we know that won't last. Research on new and better drugs is absolutely critical and another important part of USAID's strategy. We are supporting Medicines for Malaria Venture (MMV) and WHO in new drug development.

Next Steps

There is much to do. If we are to meet our goal of halving Malaria by 2010, all of us, our esteemed partners from African governments, health institutions and our global partners must act together through the opportunity offered by the Global Fund and through the Roll Back Malaria partnership at all levels, most importantly in countries, to deliver the tools we have in hand, to develop new tools, and to fulfill the promise of coordinated and concerted support to countries.

The key to success will be to work together in improved and more effective ways. There is no silver bullet, no single intervention that is the answer to malaria. We must put in place a comprehensive approach to malaria that includes prevention, effective treatment and research for better tools. I am pleased to be here today with so many of our partners in this fight. As we consider the plight of those who face this deadly disease, we must act rapidly with the most effective methods of prevention and treatment. We must continue to respond to rising expectations for health care and find the best treatment available for all.

Tuberculosis (TB) Background

Tuberculosis (TB) is an ancient disease. While a cure has been available for over fifty years, TB still kills more than two million people every year. Each day, nearly 25,000 people develop active TB and 5,000 die from their disease. Approximately one-third of the world's population or two billion people are infected with TB. According to the 2004 WHO Global Report on TB, in 2002 there were an estimated 8.8 million new cases of TB, of which 3.9 million were sputum smear positive (Sputum smear positive TB cases affect the lungs, are the most infectious and therefore the most responsible for transmission of the disease (SS+) or "infectious" TB). In 2002, the global incidence rate (per capita) of TB was growing at a rate of 1.1% per year, and the number of cases was growing at 2.4%.

The global resurgence of TB has been fueled by increasing HIV/AIDS prevalence, inadequate public health systems, and emerging resistance to anti-TB drugs. Persistent poverty, crowded living conditions, and delayed diagnosis and treatment contribute to transmission of the disease.

TB threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development. An overwhelming 98% of the two million annual TB deaths—and 95% of the new TB cases each year—occur in developing countries. On average, TB causes three to four months of lost work time and lost earnings of 20–30 percent of household income. For families of persons who die from the disease, the impact of TB is even greater as about 15 years of income is lost due to premature death. In developing countries, the impact of TB on the family is even more important as TB generally afflicts the most economically active segment of the population between the ages of 15 and 54.

Treating TB through the Directly Observed Treatment, Short-Course (DOTS)

Much progress has been made since The Stop TB Partnership (of which USAID is a member) was launched in 1998. The Amsterdam Ministerial Conference on Tuberculosis and Sustainable Development held in March 2000 established global targets of 70% TB case detection and 85% treatment success rates in SS+ pulmonary TB cases to be achieved by the year 2005 in the 22 High Burden Countries (HBCs). These countries together account for 80% of the world's estimated cases, and served to catalyze governments and donors to address TB.

The Stop TB partners and countries have endorsed The Directly Observed Treatment, Short-Course strategy as the most effective strategy available for the treatment and control of TB. The DOTS Strategy has five components: political commitment; passive case detection among patients seeking care at health facilities and diagnosis using sputum smear microscopy; standardized short-course treatment with direct observation of therapy at least in the initial phase; assurance of an uninterrupted supply of high quality drugs.

The number of countries implementing DOTS increased from 112 in 1998 to 180 in 2002 and one high burden country (Peru) reduced TB incidence sufficiently to graduate from the list of 22 HBCs. The Partnership has grown to include over 200 donors, non-governmental organizations (NGOs) and other institutions, which demonstrates the strong global commitment to combat TB and to collaboration in that effort.

However, recent analysis of global TB trends and progress in DOTS implementation indicates that without an acceleration of DOTS expansion and program

strengthening, these global targets will not be achieved for many years to come. Reported global DOTS coverage of 69% masks the reality that many people, even in areas where DOTS is reportedly available, lack true access to DOTS. While the overall treatment success in DOTS areas is 82% (2001 cohort) about 31% of the world's population resides in non-DOTS areas where treatment success averages just 40%. Globally, just 44% of estimated SS+ TB cases were detected in DOTS and non-DOTS programs combined in 2002. At the current rate of progress, the global target of 70% case detection will not be reached until 2013.

Tuberculosis in Africa

An estimated 26% (1.149 million cases) of the global TB burden is attributed to the Africa region, where nine of the 22 HBCs are located. The region is second behind South East Asia (33%) in terms of the burden of TB. Although the rate of increase in TB incidence has been slowing in the Africa region as a whole since the mid 1990s, Eastern and Southern African countries with a high HIV prevalence have reported increased rates of TB case notification of approximately 7% per year. HIV/AIDS is driving the TB epidemic in the countries of these two sub-regions of Africa where the HIV prevalence among patients with TB is approximately 24 to 79%.

Africa has made steady progress in implementing DOTS, although there are some serious constraints to progress. First and foremost, is lack of qualified staff—both at the central level of national TB programs, as well as at the peripheral-level facilities where DOTS services are provided. Second, infrastructure is inadequate and primary health care systems are weak, including a lack of transportation, poor communication, unreliable utility supplies, inadequate equipment and buildings. Third, laboratories are weak in many countries, including access to and quality of diagnostic services. Fourth, increasing TB–HIV co-infection is causing a rise in TB incidence rates, contributes to low cure rates, and poses a serious challenge as DOTS programs struggle to effectively manage the high volume of TB cases. Fifth, weak or wavering political commitment—both at the central and peripheral levels—continues to obstruct TB control in some countries. Sixth, monitoring and evaluation, including reporting and recording—remain weak in many countries. Finally, while decentralization has been underway for many years, in a number of countries, it continues to be a constraint to TB control due to a lack of capacity at the peripheral level.

USAID's Response

USAID currently supports programs to expand and strengthen DOTS in eleven African countries (USAID assists DOTS programs in Angola, Democratic Republic of Congo, Ethiopia, Ghana, Kenya, Nigeria, South Africa, Uganda, Malawi, Senegal, and Sudan) including six of the nine African countries listed among the 22 HBCs. Illustrative activities supported in these countries include training of health personnel, strengthening of laboratory services and provision of laboratory equipment, development of guidelines and training materials, and technical assistance to strengthen program planning, monitoring, evaluation, and supervision.

For example, in the Democratic Republic of Congo, USAID provides approximately \$1.2 million per year to support DOTS expansion and strengthening in three provinces, and strengthening of national and provincial-level human resource capacity and program management. Political commitment has been strengthened at the national level, as evidenced by the assignment of additional personnel to the central unit of the national TB program, a waiver of customs duties for a recent shipment of anti-TB drugs, and the signing of two decrees by the Ministry of Health assuring that anti-TB drugs would be free of charge. A national TB task force has been officially approved by the government, and the formation of provincial TB task forces is underway. USAID funding has also supported technical assistance, training, monitoring and supervision, and needed diagnostic equipment. The results of USAID's program are evident. DOTS coverage has reached 70%. The treatment success rate and the SS+ case detection rate both increased 10 percent following the initiation of USAID's program.

In South Africa, USAID's program initially focused on Eastern Cape province, and subsequently expanded to Mpumalanga, Northwest, KwaZulu-Natal and Limpopo provinces. The program focuses on increasing the availability of DOTS, improving the quality of DOTS services, increasing demand for DOTS through information, education and communication (IEC), and improving the TB program management at the national and provincial levels. Assistance is also provided to implement an electronic TB registry, prevent and control TB transmission in hospitals, support co-ordinated activities between the HIV/AIDS program and the TB program, and for studies to measure the rate of anti-TB drug resistance. Clear progress has been

achieved. DOTS coverage has increased from 66% to 98%, and the SS+ case detection rate has reached 97% as compared to 71% prior to the initiation of USAID's program. While the treatment success rate improved from 60% (1999 cohort) to 65% (2001 cohort), this indicator remains far below the desired target of 85%. Efforts are underway to more fully engage NGOs and the communities in the provision of observed treatment and the tracing of patients who default.

USAID's Technical Leadership

In addition to our direct support for improving TB treatment programs at the country level, USAID also provides assistance to support DOTS programs in Africa through several global mechanisms and partners such as the STOP TB Partnership and the Global TB Drug Facility (GDF). USAID is actively involved in the STOP TB Partnership—the Agency is a member of the Partnership coordinating board and USAID technical personnel are members of all STOP TB technical working groups. USAID funding to the STOP TB partnership and WHO is assisting countries such as Kenya and Uganda to improve laboratory capacity, to test public-private mix DOTS models, and to assess the impact of IEC on TB case detection.

The Agency provides funding and technical support to the GDF, and we are the second largest donor to the GDF. Since it was launched in 2001, the GDF has raised and committed \$39 million for grants for anti-TB drugs. Of the 49 grants awarded by the GDF, 29 (59%) have been awarded to countries in Africa. Through the GDF and USAID's technical assistance programs countries and NGOs also receive technical assistance and training to strengthen the management of anti-TB drugs. They can also purchase anti-TB drugs through the GDF direct procurement mechanism, and therefore take advantage of the highly competitive pricing and good quality products that are available through the GDF.

In this respect, the GDF is a perfect partner to the GFATM. Using funding provided by Global Fund grants for TB, countries and organizations can purchase TB drugs through the GDF direct procurement service.

Battling Multi-Drug Resistance

USAID is also working to address the problem of multi-drug resistant TB (MDR TB). We support country surveys to measure the magnitude of TB drug resistance as part of the on-going WHO/IUATLD Global Project on Anti-TB Drug Resistance Surveillance. To date, USAID has supported surveys in 15 countries or sites (including South Africa), with studies in 16 more countries ongoing or planned (including Ethiopia and Democratic Republic of Congo). We also support an effective response to MDR TB by funding DOTS Plus for MDR TB pilot projects in a number of countries and settings, focusing on countries with the most serious MDR TB problem such as Russia (Orel and Ivanovo oblasts), and the Baltics (Latvia, Estonia, and Lithuania), and Kazakhstan. We provide funding to support the work of the STOP TB Green Light Committee (GLC). The GLC provides technical assistance and monitoring of DOTS Plus for MDR TB pilot projects. So far, the GLC has approved DOTS Plus pilot projects in 11 countries and another 14 applications are under review. DOTS plus projects that are approved by the GLC are eligible to purchase second-line anti-TB drugs at lower prices than on the open market. Finally, we support a network of supra-national reference laboratories that provide the necessary quality control for anti-TB drug susceptibility testing, and we are supporting training and operations research in hospital infection control to help reduce the risk of transmission of MDR TB in clinic or hospital settings.

USAID and Global Fund Support For Africa

USAID missions work closely with the Global Fund to Fight AIDS, TB and Malaria (GFATM) by leveraging mission funded programs with the substantial funding provided by the GFATM. Twenty-five African countries have been approved for 2-year TB grants totaling \$109,330,269 in four rounds of grants awarded by the GFATM. The total 5-year maximum for these grants is \$223,148,330. In addition, three countries—Rwanda, South Africa and Tanzania—have been approved for HIV/TB 2-year grants totaling \$81,869,831. The 5-year maximum for these grants is \$269,060,932. USAID missions participate in the Country Coordinating Mechanisms, assist with grant proposal writing, and help countries prepare implementation and monitoring and evaluation plans for these grants. Through USAID technical partners such as the TBCTA and others, USAID missions provide support for technical assistance, capacity building and monitoring and evaluation to help the grant-recipient countries to effectively implement and manage GFATM grant-funded programs and activities.

In addition to the programs highlighted above, activities to strengthen TB-HIV/AIDS care are included in the programs of all 12 African countries that are the focus of the President's Emergency Plan. TB-HIV/AIDS services are a critical com-

ponent of the basic care package of services provided to People Living with HIV/AIDS (PLWHA). Funding provided by the Emergency Plan will support: isoniazid preventive therapy for persons with HIV/AIDS who do not have active TB; improving the treatment of TB, including DOTS services, for PLWHA who have active TB disease; provision of HIV counseling and testing to persons with TB; and screening for TB, and referral of TB suspects, among persons attending HIV counseling and testing centers. Assistance is also being provided for the development of policies, guidelines, and training materials, and for the training of personnel to implement the aforementioned services. FY 2004 country operational plans have included an average of \$1 million for TB-HIV/AIDS services such as those described above.

Finally, USAID is working actively to prevent and address multi-drug resistant tuberculosis. USAID is currently or plans to support drug resistant surveys in a number of countries, including in South Africa, Ethiopia, and the Democratic Republic of the Congo. We are supporting operations research on improved DOTS plus programs including in South Africa. We provide funding to support the work of the STOP TB Green Light Committee (GLC). The GLC provides technical assistance and monitoring of DOTS Plus for multi-drug resistant TB pilot projects. We are supporting training and operations research in hospital infection control, since patients with MDR TB sometimes need hospitalization. To sum up, the best approach to preventing MDR TB is to make sure good DOTS programs are in place.

Mr. ROYCE. Let me ask you, in your testimony you mention that the goal was to cut malaria in half by 2010 from the levels that existed in 2000. From the evidence, at least on the continent of Africa, we are not headed in the right direction.

I wanted to ask you specifically which AID program has been most successful in fighting malaria and in fighting TB, and which have been least successful, and what lessons, maybe, we have learned by that. Maybe part of that goes to how we quantify this.

One of the commentaries that we get from critics of USAID is the charge that the focus is on reporting inputs, for example how many bed nets have been provided, but not on results. Because they say, well, the number of malaria cases or TB cases reported, that would be the result that you would want to look at, and if that result is increasing, then clearly quantifying results must be a challenge for USAID.

So I throw out that criticism for your response.

Dr. PETERSON. I think it is important to remember that the escalation of malaria as a problem began in the early 1990s, so both by the time USAID was given more resources to respond and as Roll Back Malaria became an entity, it was the response to an already rapidly-growing problem. So we are coming in when the horse is already out of the barn and having to go back and look at it.

I would also say that there are three major drivers for why it has been harder in Africa to get hold of the problem than we would like. Number one is that Africa, unfortunately, has a lot of crisis and conflict countries. It is very clear, and you can measure how much higher the malaria burden is in those countries that are in conflict and crisis. It makes perfect sense. They are both unable to get access to prevention or treatment modalities.

In our child survival countries, 65 percent of the countries have been in conflict or crisis in the last 5 years. That is a huge driver for all of the communicable diseases. Similarly, even separately from the crisis countries in conflict, we have seen economic decline and problems with governance and health systems throughout Africa, and, again, you see that reflected not just in malaria disease and death, but also in rates of immunization and diarrheal deaths across the board. So you have declining health systems for both

economic and governance reasons. I think we are just beginning to realize that the upsurge in HIV/AIDS is responsible for some of the increase in malaria deaths in Africa as well.

So there are at least three very strong drivers for why we have not been able to quickly contain this epidemic that was already going forward.

I would also again say that when something is an infectious disease and is on the upsurge, it takes a while to bring it to stability and turn it around. Roll Back Malaria and USAID investments have been growing over the last few years, but it is only very recently that we have had resources to really implement in these areas.

As far as what has been most successful versus least successful, I will say that it is clear—both in the international consensus and as we look at successful programs—that the countries with integrated programs are doing the best. We can't just do one thing. That is what we did in the 1950s and 1960s, we used a single modality and we need to be able to bring all of the different modalities to bear on the problem.

Mr. ROYCE. One last question I wanted to ask you. You mentioned insecticide treatment, again returning to the arguments put forward by some of the critics of the program. They say many experts believe that beating malaria requires several different interventions.

Can there be an effective anti-malaria strategy without DDT or other insecticides in your view? Of course, the other question is, does the limited use of DDT, in a home in this, case pose environmental or health risks? I wonder if there were any studies conducted of the environmental impact in South Africa or in Zambia on their limited use of DDT and what those consequences were.

Dr. PETERSON. I would have to get back to you on whether there are studies on the environmental risk. It is very clear that the malaria risk is higher. And the malaria health risk is higher than any risk of DDT in that sort of minimal exposure that we have. So the risk of dying of malaria is certainly far greater than any risk from using indoor residual spraying of DDT in homes. There is a role for the IRS spraying with DDT and other insecticides.

[The information referred to follows:]

RESPONSE SUPPLIED IN WRITING BY THE HONORABLE E. ANNE PETERSON TO QUESTION ASKED DURING THE HEARING BY THE HONORABLE EDWARD R. ROYCE

STUDIES OF ENVIRONMENTAL RISK OF DDT

Pesticides are classified by EPA according to their toxicity in one of four categories—high (danger), moderate (warning), low (caution), and very low (caution). DDT is in the moderate category. Following a review of available evidence, The WHO Study Group on Vector Control and Other Mosquito-Borne Disease, in 1995 (WHO TRS 857, Geneva 1995) concluded that there was “no convincing evidence of adverse effects of DDT exposure as a result of indoor residual spraying as carried out in malaria control activities” and stated further that “there is therefore at this stage, no justification on toxicological or epidemiological grounds for changing current policy towards indoor spraying of DDT for vector-borne disease control.” The study group further concluded that “DDT may therefore be used for vector control, provided that all the following conditions are met:

- (i) It is used only for indoor residual spraying
- (ii) it is effective
- (iii) it is manufactured to WHO specifications

(iv) necessary safety precautions are taken in its use and disposal”

Additional factors that may be considered

- “ (i) Cost involved in the use of insecticides
- (ii) Role of insecticides in vector control
- (iii) Availability of alternative vector control methods, including alternative insecticides
- (iv) Implications for vector resistance
- (v) changing public attitude to pesticide use
- (vi) further epidemiological investigation and studies”

In 2000, The 20th WHO Expert Committee on malaria re-examined the conclusions of the WHO Study Group and endorsed them as still valid (WHO, TRS 892, Geneva 2000).

Dr. PETERSON. The question really is in which situations, how much. Could we do treatment of malaria on a national scale without DDT? Perhaps. But there are places where it is very appropriate to use the indoor residual spraying. South Africa is a good example. This is a country that does not have a heavy burden of malaria; it is much more seasonal and has a lot of urban settings with a lot of infrastructure. It makes it easy and appropriate to use IRS and it has been very successful there. It is best to use as many different modalities as we possibly can to address malaria.

So, again, I would say our evidence is that an integrated approach that brings the access to treatment, the nets, the preventive treatment of pregnant mothers, and possibly for children under 5 as well, and using DDT appropriately are all what we need to put together into a single package.

Mr. ROYCE. Thank you, Dr. Peterson.

We will go to Mr. Payne.

Mr. PAYNE. Thank you very much for your very thorough testimony.

I just have a few questions. We know that we had a cure for TB 60 years ago. And 10 years ago there was a declaration that we should have a—WHO said we need to deal with it severely. But we have 8 million people still being infected every year. I am wondering why you feel we are losing the battle on TB so greatly?

The other question is, we know there is an intersection between TB and HIV and AIDS, and there are some advocates that say we should try to more closely interlink the strategies and have a joint strategy. I wonder if there are any dangers in trying to implement a joint strategy.

Just briefly, the question of the nets being used, is it economic or educational? Are people just unaware of the net thing and don't do it, or is it an economic question?

Since time is limited, I will just let it go there. Maybe others can have an opportunity to ask questions.

Dr. PETERSON. Okay. On TB, why are we losing the battle? Clearly, we thought we had won the battle—both in the U.S. and internationally—decades ago. What happened is when something becomes less noticeable, it becomes lower priority, and even in the U.S. we saw funding decline and then TB begin to come back. So that is certainly a factor internationally.

We also have drugs, but we haven't had a new TB drug for 30 years. These are drugs that have been around for a long, long time. Even now used in combination, we should not be surprised that we begin to have drug resistance.

So between being under-resourced, drug resistance problems, and settings that increase transmission, such as Russia where there is contact between the prison population and the public where you have a very ripe situation for disease transmission. Something like a drug-resistant strain of TB in that setting has a great opportunity to become widespread.

Again, if you remember from our history, TB is a disease of poverty and that is still where we are seeing it. We have not dealt with some of the underlying conditions. So we should not be surprised that TB is both still a problem and is coming back, given the resources we brought to bear on it, including not having any new drugs in a very long time.

We definitely should be working on the integration between TB and HIV. We are doing that in encouraging joint proposals to the Global Fund to Fight AIDS, TB, and Malaria. I will say that from my own experience there, I think the countries are realizing that if they ask for money separately, they get to bring more grants to the Global Fund and therefore they get more money. So we have actually seen a decrease over time in joint AIDS–TB grants.

What we are thinking of doing, and it has been discussed at the Board, is requiring that as a country brings a proposal forward on HIV, if they have lots of TB as well, that they must say how they are going to address TB for their HIV/AIDS programs. And if it is a TB grant, how they are going to address AIDS, and begin to find that nexus.

We are working on policies to identify the other disease in a particular setting. If we are doing HIV voluntary counseling and testing, we are looking for and addressing TB; similarly in Africa, when a TB patient is identified, we ought to be testing them for AIDS. How do we get in place this kind of policy?

In the PEPFAR initiative, very similarly, we have been—and I don't know if it is being done anyplace else in the world—very specifically building in policies to deal with malaria within HIV-positive populations. Many places do it for TB but we are doing those same things for malaria.

As far as why not the nets or why hasn't it moved forward, there are programmatic stumbling blocks such as getting production up, getting regulatory access to the insecticides in each country, and getting textile producers to make the nets. What we are finding is that the acceptance of the nets is not nearly as much of a problem as the availability, and that is a little counter to what we had previously thought.

The retreatment of nets with insecticide after it has dispersed has been an obstacle to scale-up, but we have been investing in it and should soon have long-lasting treatment nets that do not need any retreatment. So it would be something you can provide once and it would be good for 5 years. That should make a really big difference in our ability to scale-up availability and, hopefully, acceptability of the nets.

Mr. ROYCE. Mr. Tancredo.

Mr. TANCREDO. Thank you, Mr. Chairman.

One question only, and that is: Given the fact that, as with all these kinds of issues, there is a scarcity of resources available to

us and we have two places to go with what we have—one is prevention, one is treatment—what do we do? How much goes where?

Dr. PETERSON. Really both.

Mr. TANCREDO. And why?

Dr. PETERSON. Malaria and TB are very similar. We need to do both prevention and treatment.

Mr. TANCREDO. Well, but, I mean, we can't. We can't. We do not have enough money, certainly, in the budget of the United States to do both. What can we do with what we have got if, in fact, our resources are limited? Which should we concentrate on?

Mr. ROYCE. We will go to Dr. Peterson for a reply, and then to Ms. Lee.

Dr. PETERSON. Prevention is always the most cost-effective way of addressing a disease. In malaria, access to treatment also helps with prevention and it does immediately reduce deaths. So there is a very appropriate need to scale-up our treatment at the same time we do prevention.

If we only do the bed nets or the indoor residual spraying, in the face of mothers who come in with their babies dying, we will not be addressing the both urgent needs and the felt needs as well as the transmission.

The intermittent presumptive treatment of pregnant women is both treatment and prevention, so the differences between those get a little murky.

In TB, we haven't as many preventive modalities. We truly are looking at going and treating people, since it is an infectious disease, so that they do not spread it, and then identifying the contacts who might also be at risk and taking care of their potential for disease.

Mr. ROYCE. We will now go to Ms. Lee, after which we have a 10-minute vote on a substitute. We have about 4 minutes left in that vote, then we have 10 minutes of debate and a 15-minute vote after that. We will come back for the second panel, which will give us about 25 minutes for the second panel.

Ms. Lee.

Ms. LEE. Thank you for calling this hearing, Mr. Chairman.

Let me say with all due respect to my colleague Mr. Tancredo, I guess there are resources, and we shouldn't have to make the choice between treatment or prevention. We have given billions of dollars in tax cuts, and billions are going for senseless wars. So I think what this boils down to is a matter of priorities and where we put our resources.

Let me just ask you a question about the Global Fund. You mention it, and since we don't have a lot of time, you may not be able to respond, but maybe in writing you can. I am trying to, for the life of me, figure out why—knowing that the Global Fund can get the money out quickly, knowing it is a multilateral effort and the U.S. should be in the lead on this—why in the world aren't we pushing for more than \$200 million or \$500 million a year? We should be pushing for a couple billion a year if we are going to really address combating malaria, TB and AIDS. I don't understand why the Administration doesn't get it. Maybe you do.

Dr. PETERSON. Let me just say it is very clear to me in my work in AIDS, as well as TB and malaria, that we need the Global Fund

to succeed. It needs to succeed with good support in-country by our bilateral programs. It is equally clear to me it won't succeed if it does not have the sufficient resources from bilateral programs.

The U.S. Government can't do this fight alone and the cap of 33 percent has shown us that the other donors are not stepping up to the plate even to match what we have currently. So we are trying desperately to increase resource mobilization and get them to step up to the plate with us. I think the Administration is striking an appropriate balance between those two different modalities.

Ms. LEE. You don't think we need to request more for the Global Fund?

Dr. PETERSON. I think we need to request the rest of the world to begin to address it as much and as hard as we have.

Ms. LEE. But we don't need to put \$1 billion a year in the Global Fund. No?

Thank you very much.

Mr. ROYCE. Excuse me, Congresswoman Lee. Would you like to come back and we can continue?

Ms. LEE. I would. Sure.

Mr. ROYCE. We will just recess and come back, and that will give the other Members an opportunity to ask more questions of you, and we will join you on the Floor in a minute. We stand in recess.

[Recess.]

Mr. ROYCE. The Committee will come to order.

I wanted to follow up with one question. We talked a little bit about the incidence of the use of the insecticide netting. It was only 2 percent. I was wondering why such a low incidence. Why is it difficult to get adoption of this as a methodology for African children? Why don't they want to sleep under the insecticide-treated netting?

Dr. PETERSON. We need to remember that the insecticide-treated bed nets as a prevention for malaria is actually a new intervention. We only had the studies that showed that treating the nets with insecticide would have these profound reductions in malaria in about 1998. So people have been using nets, and sometimes treated nets, more for the nuisance factor and some for malaria. But we didn't have the data.

We talked in the beginning about having data-based interventions. We didn't have the data that showed use of these insecticide-treated nets would give you the profound impact on malaria to be able to bring them forward as major programs for malaria implementation. Then you have to find ways to produce and get the insecticides in through countries. You would think it would be simple, but we have had countries that would not let us bring the insecticide in due to trade barriers, and that slows down production and therefore implementation.

Mr. ROYCE. Which countries have resisted?

Dr. PETERSON. I know Nigeria for one was a problem when I visited there a year ago and I am sure there were others. I would have to have my staff get that for you.

[The information referred to follows:]

RESPONSE SUPPLIED IN WRITING BY THE HONORABLE E. ANNE PETERSON TO
QUESTION ASKED DURING THE HEARING BY THE HONORABLE EDWARD R. ROYCE

TRADE AND OTHER BARRIERS TO INSECTICIDE IMPORTATION AND USE

Nigeria, Cameroon and Ethiopia have high taxes and tariffs on ITNs or on their components—insecticides, netting and netting materials, finished nets, etc. In addition, there are other regulatory barriers to insecticide-treated nets. For example in Ethiopia and Mozambique, only one insecticide is registered, making it more difficult to expand the availability of ITNs.

Mr. ROYCE. With your cooperation, we might allow the Members of the Committee to submit questions.

I wanted to go back to Congresswoman Lee for any questions she might have.

Ms. LEE. Thank you very much, Mr. Chairman.

I want to ask you more about the relationship between the Global Fund and our bilateral activities, and, in fact, your response with regard to the rest of the world actually, given that the Global Fund is the multilateral fund. We are the main country stepping up to the plate. What do you think is the problem right now?

I mean, I think whether other countries contribute or not, we want everyone to contribute. This pandemic—the HIV/AIDS, malaria, tuberculosis—these diseases are taking so many lives that I don't want to see us wait in terms of a robust response. And \$200 million a year for the Global Fund is not robust, whether or not other countries kick in.

Dr. PETERSON. One of the things we struggle with in other areas, but especially with an infectious disease pandemic, is the needs are always bigger than the resources. What is very clear, and what has led to the advent of many of the multilateral alliances, is that the countries clearly can't take care of these problems themselves.

The U.S. Government can't take care of fixing the entire world, even if we were to take all of our resources. Frankly, the rest of the world wouldn't want us to do it on a unilateral basis. Then when you get to the Global Fund and the financing of it, we are in this very sort of strange dynamic where they want us to give more money but they do not want it to be solely a U.S. fund.

But they are not stepping up to match our contributions. The U.S. has been very, very active in trying to encourage other countries; big countries, little countries. Frankly, one of the most innovative ones that I saw was the community of people living with the diseases start reaching out to their whole network asking for \$1 contributions to begin to try and draw down the U.S. dollars.

The Global Fund was supposed to be additive to other endeavors. This is what we desperately need. And I know it is what you really want as well. Not to substitute. It is only, I think, by really being serious about other countries also needing to step up to the plate and assuring that the in-country national Governments cannot reduce their own expenditures for AIDS, tuberculosis and malaria and just rely on outside funding. We have to have every one participate if we are going to make the Global Fund succeed and really have more resources.

Mr. ROYCE. Thank you, Dr. Peterson.

I would like to, if I could, go to our next two witnesses, and that way we may be able to get their testimony in. Thank you, Dr. Peterson.

Mr. ROYCE. We are going to go to Dr. Allan Schapira and Dr. Roger Bate as our next panel and ask them to come forward as our second panel. We have 15 minutes before this vote, so I am going to ask you both to summarize, as I asked Dr. Peterson.

Dr. Allan Schapira is the Coordinator of the Strategy and Policy Team at the Roll Back Malaria Department of the World Health Organization. He has been involved in health care projects in Botswana and Mozambique. Dr. Schapira has spent much of his professional life working on malaria treatment and anti-malaria drug resistance. He has written many articles in scientific publications and I would like to thank him for briefing us today on behalf of the World Health Organization.

Dr. Roger Bate is Director of Africa Fighting Malaria and a visiting fellow at the American Enterprise Institute. He has written several scholarly papers and scientific articles on health issues and conducts research on water policy in developing countries. In the past he has advised the South African Government on water policy, as well as founding the Environment Unit at the Institute for Economic Affairs. Dr. Bates has also co-founded the European Science and Environment Forum.

Dr. Schapira.

**STATEMENT OF ALLAN SCHAPIRA, M.D., COORDINATOR,
STRATEGY AND POLICY TEAM, ROLL BACK MALARIA DE-
PARTMENT, WORLD HEALTH ORGANIZATION**

Dr. SCHAPIRA. Thank you, Chairman Royce and Members of the Subcommittee, for this opportunity to brief you on malaria on behalf of WHO and its Rollback Malaria Department.

Today's hearing is also about tuberculosis and I respectfully request that a forthcoming briefing statement from a colleague, Paul Nunn of the Stop TB Program, also be included for the record.

Mr. ROYCE. Without objection, it will be.

Dr. SCHAPIRA. Thank you very much. I will try to be brief, and it will be easier for me because of the review that has already been given by Dr. Anne Peterson.

As one picture can say more than a thousand words, I brought a few pictures. Please take a look at the pictures which I attached to the written statement.

If you would see the first one, it shows a little girl, Adhiambo, 16 months old. She lived in western Kenya near Lake Victoria. In April of this year, she developed a fever. Her mother gave her tablets for treating malaria, and these tablets had been bought in a shop.

[The photo referred to follows:]



Dr. SCHAPIRA. Adhiambo did not get better. The next day she stopped talking. The mother decided to take her to a hospital. It took 6 hours to get there. At the hospital the right treatment was given but Adhiambo did not get better. She died the next morning. If she had received effective treatment in time back in the village, she would not have died.

Now, how does malaria kill? Look at the next picture. Parasites are transmitted by mosquitoes, injected through the bloodstream. Then what can happen in the bloodstream is that the parasites clog the vessels, especially the vessels to the brain, causing cerebral malaria. That is what happened in the case of Adhiambo. Or the parasites can destroy the red blood cells, causing profound anemia. Sometimes you have both.

[The photo referred to follows:]

Cerebral malaria



Severe anaemia

**The lethal duo**

Dr. SCHAPIRA. Children who survive malaria may be harmed despite surviving. Repeated episodes of fever and anemia take a toll on their development. It impairs their schooling and growth into productive adults.

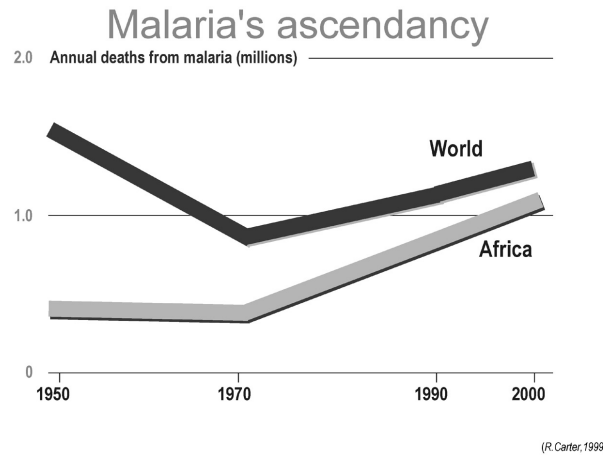
Also, women are particularly vulnerable during pregnancy when the disease can lead to anemia, low birth-weight babies, and, again, increases the risk of death in infancy.

Outside Africa, and also in certain parts of Africa—especially the highlands—it is not so much the children as the adults who are vulnerable. But in all those areas, it is the poorest areas, it is the most remote and underserved areas where there is most malaria, and the disease can kill the breadwinners in the family.

Everywhere malaria is a cost, an accompaniment to poverty and underdevelopment. In Africa specifically, a very solid study has led to an estimate of 12 billion United States dollars lost per year as income which otherwise would have been there. One of the reasons for this is not only lost income due to disease, but also the fact that malaria keeps investment out, both in Africa and other parts of the world.

The next photo on page 2 shows the rise of malaria, and you will see that it has risen in the world in the last 10 years because it has risen in Africa. In the early 1990s when I joined WHO, coming from Africa, we actually did not have very, very clear ideas about what to do. We had to invest a lot in field research. The field research did help us to find out how to identify a practical package of cost-effective interventions.

[The photo referred to follows:]



Dr. SCHAPIRA. Just look at the picture of the mosquito there. It is not any mosquito, it is an *Anopheles gambiae*. It is the main malaria vector in Africa. It is very hard to beat, very, very adaptive, can breed in any kind of water collection.

[The photo referred to follows:]



Dr. SCHAPIRA. So that is the enemy that we are going to war against, not the only enemy, but the main enemy. We need to fight mosquitoes. There is no other way to control malaria without having an element of mosquito control involved. There are lots of methods for doing that but two of the most important ones are insecticide-treated nets and indoor residual spraying.

You see on page 3, in the top picture, a mother and child sleeping under an insecticide-treated net.

[The photo referred to follows:]



Dr. SCHAPIRA. This intervention, as has been said already, has been proven in very careful, controlled, large-scale trials to reduce all child mortality in Africa by around 18 percent. It is one of the most cost-effective of all public health interventions. Only measles vaccinations and a few others are better in terms of cost-effectiveness.

These trials in Africa have been famous, but nets are not only effective in Africa. We mentioned Vietnam as an example, where I worked myself for 5 years. Vietnam had 10 million people, most of the population at high risk, under insecticide-treated net treatment. And it took them 5 years to reduce malaria mortality by a very impressive figure of 97 percent, from 4,000 down to 300 over a period of 5 years, mainly with insecticide-treated nets, but they were spraying in a few areas also. There was also effective drug treatment available.

Now, regarding indoor residual spraying illustrated in the next picture.

[The photo referred to follows:]



Dr. SCHAPIRA. As Dr. Peterson mentioned there is a very good review of trials showing that, by-and-large, these two methods are equally effective; where one works, usually the other one also works. One may be a little better in some places, the other a little better in other places.

What is the big difference? The difference is nets are attractive. People like them. Nets get integrated into the culture and people go on using them.

Spraying, as the picture shows all too clearly, requires that a stranger has to get into the house. It has to be done very properly by someone trained to do it. While he is spraying inside the house, whatever is in the house has to be put outside for the neighbors to look at. Sometimes the spray also smells; sometimes it leaves a visual deposit. The fact is in many countries where spraying programs have gone on for many years, people have locked their doors when the spray man comes by. Then you get coverage down to 20 percent or something like that, and then the investment is lost. For insecticide-treated nets, at least so far, we have not seen that kind of development over the years, and it is now 15 years that I have followed the Vietnamese program. People are happy to get their nets and to be treated.

However, spraying does have an advantage over nets. It is almost always more rapidly effective. If you have an epidemic, if you have an emergency, and you need to get things done as quickly as possible, then you go for spraying. Then, after that, you can see whether to continue, whether to put in nets or something else instead of it.

About treatment: I think I should just mention, as has been explained, that chloroquine no longer works. It has to be replaced as quickly as possible by something else. The best replacement that we have is artemisinin-based combination treatments. It costs about 20 times as much, but for treating a youngster, the cost would have been around \$1 U.S., which I think is a laughably small amount. But, as those who know Africa can appreciate, for the rural family in an area with no economic development activity, \$1 is not a trivial amount. It is very dubious whether Adhiambo's mother would have been able to buy it even if it had been available in the shop at the cost of \$1.

So what do we need to do with the treatments? Well, they must be made available through the public sector that needs to provide leadership, training and regulation. But we know that, and it is not only Africa, the public sector cannot reach all people. They cannot have a clinic in every village.

What we have seen is that shops actually can deliver services if some training is given. So we need to make the ACTs, the new treatments, available with a solid subsidy, but also through the private sector.

We have been talking about the main issues now in prevention and treatment of malaria. Certain interventions, preventive treatment in pregnancy, are also very important. We are now working more intensely on estimating what are the real costs of controlling malaria in the world.

Everything is more difficult in Africa, but the job of estimating the cost is actually easier for Africa because of the distribution of

malaria there. We are at the moment at an estimate of around \$2 billion U.S. per year. Of that, approximately \$300 million would be needed per year for providing free insecticide-treated nets to all pregnant women and to all children within the 1st year of life.

For example, together with an immunization campaign, very well free nets could be used as a reward for completing the immunization schedule. By such a scheme it would be possible within a few years to have provided enough nets to have all children covered with nets.

We said \$300 million for the insecticide-treated nets; \$1 billion for the ACTs, which are currently rather expensive and have to be given for all fever cases, but the prices of which are likely to go down somewhat over the coming years because of the economies of scale, new technologies and so on. It leaves around \$700 million U.S. that need to be used for spraying in certain areas, other measures necessary for epidemic control and for training, infrastructure and the very important element of training and evaluation.

I am about to wrap up. I know that all of you in this room are committed to helping Africa. I hope that you are becoming convinced that fighting malaria effectively is among the things that can be done, and that it is among the things that should be done in Africa for humanitarian reasons; but not only for humanitarian reasons, also in order to remove one of the main economic obstacles to development.

Thank you very much.

Mr. TANCREDO [presiding]. Thank you.

[The prepared statement of Dr. Schapira follows:]

PREPARED STATEMENT OF ALLAN SCHAPIRA, M.D., COORDINATOR, STRATEGY AND POLICY TEAM, ROLL BACK MALARIA DEPARTMENT, WORLD HEALTH ORGANIZATION

MEETING THE MALARIA CHALLENGE

I. INTRODUCTION

A bright, lively two-year-old boy spikes a fever one evening. Suddenly he loses consciousness, and his body begins jerking uncontrollably. His mother rushes him to the hospital, where he is treated. He regains consciousness three days later, but he is unable to speak and is blind.

His one-year old neighbor is stricken two weeks later. She dies just a day after the first sign of fever.

A pregnant woman can barely tend to her house and family because she is constantly tired. She thinks it's just a difficult pregnancy—not an infection. Her daughter is born small, weak, and anemic. It is unlikely she will reach adulthood.

A farmer is struck by yet another bout of fever, headache, and exhaustion the very week he should be getting his crops planted. By the time he has recovered sufficiently to work again, the rains have started. This year his family will struggle against famine.

Tragedies like these unfold thousands of times every day in regions where malaria is endemic. All result from the simple bite of a mosquito. And most could be averted.

Malaria is a curable disease. It is also a preventable disease. But people in affected countries lack access to prevention and treatment. That is the challenge.

II. WHAT IS MALARIA?

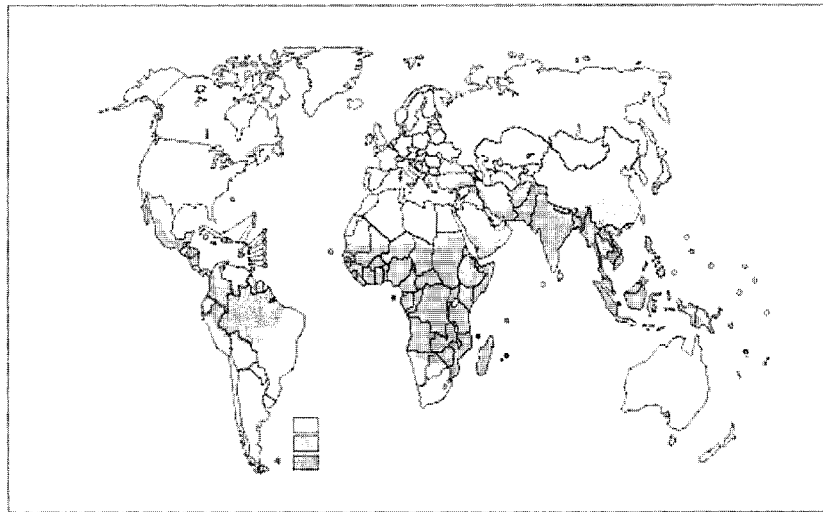
Malaria is a life-threatening parasitic disease transmitted by mosquitoes. It was once thought that the disease came from fetid marshes—a concept that gave rise to the name *mal aria*, (bad air). In 1880, scientists discovered the real cause of malaria: a one-celled parasite called plasmodium. Later they discovered that the parasite is transmitted from person to person through the bite of a female anopheles mosquito, which requires blood to nurture her eggs.

There are four types of human malaria: *Plasmodium falciparum*, *P. malariae*, *P. ovale* and *P. vivax*. *P. falciparum* and *P. vivax* are the most common and *falciparum* the most deadly type of malaria infection. *Plasmodium falciparum* malaria is most common in tropical Africa, accounting in large part for the extremely high mortality among children under five years in this region.

The malaria parasites enter the human host when an infected mosquito takes a blood meal. Inside the human host, the parasites first infect the liver and then the blood, where they multiply asexually, destroying increasing numbers of red blood cells. Some parasites in the blood develop into sexual forms that can infect a mosquito when it bites the infected person. Inside the mosquito, sexual reproduction leads to the formation of parasite forms that lodge in the salivary glands making the mosquito infective to humans.

Malaria symptoms usually appear about 7 to 14 days after the infectious mosquito bite. Typically, malaria produces fever, headache, vomiting and other flu-like symptoms. If medicines are not available for treatment or the parasites are resistant to them, the infection can progress rapidly to become life-threatening. Malaria can kill by infecting and destroying red blood cells (anaemia) and by clogging the capillaries that carry blood to the brain (cerebral malaria) or other vital organs.

III. MALARIA'S BURDEN



Above: World malaria situation. Malaria is endemic to tropical and sub-tropical regions.

Illness and Death

Today approximately 40% of the world's population—mostly those living in the world's poorest countries—is at risk of malaria. The disease was once more widespread but it was successfully eliminated from many countries during the mid 20th century. Today malaria is found largely in the tropical and sub-tropical developing countries, where it causes more than 300 million acute illnesses and at least one million deaths annually.

Ninety per cent of deaths due to malaria occur in Africa south of the Sahara, mostly among children under the age of five. Malaria kills an African child every 30 seconds—that is 3,000 children every day. Some children who survive an episode of severe malaria may suffer from learning impairments or brain damage. Pregnant women and their unborn children are also particularly vulnerable to malaria, which is a major cause of low birth weight, anaemia and infant death.

There are several reasons why Africa bears an overwhelming proportion of the malaria burden. Most malaria infections in Africa south of the Sahara are caused by *Plasmodium falciparum*, the most severe and life-threatening form of the disease. This region is also home to two of the most efficient, and therefore deadly, species of the mosquitoes which transmit the disease, *Anopheles gambiae* and *An.*

funestus. Moreover, many countries in Africa lack the infrastructure and resources necessary to mount sustainable campaigns against malaria. As a result, few have benefited from ongoing efforts over the last half-century to eradicate malaria.

Malaria has not been totally eradicated in the Northern Hemisphere. Isolated, locally transmitted cases still occur in North America, and a growing number of international travellers are contracting malaria. There are 12,000 cases per year in Western Europe. There has been a resurgence of malaria in parts of the former Soviet Union, especially in the Central Asian republics as well as in the Korean peninsula. Conversely, a number of countries, which have experienced economic growth and social stability in Southeast Asia and Latin America over the last 10–20 years have been able to reduce the malaria burden significantly.

Economic burden

Malaria keeps poor people poor. Malaria-endemic countries are caught in a self-perpetuating cycle of disease and poverty. Malaria discourages foreign investment and tourism and internal trade and adversely affects people's choice of economic activities.

Malaria has been estimated to cost Africa more than US\$ 12 billion every year in lost GDP, even though it could be controlled for a fraction of that sum.

In tropical Africa malaria is typically responsible for 40–50% of all hospitalizations and outpatient visits. People exposed to malaria may spend as much as a quarter of their incomes on anti-mosquito measures, medical visits, medicines, laboratory tests and funerals for victims. They are less productive and lose income because of absences from work or inability to plant and harvest crops. Malaria also hampers children's schooling and social development through both absenteeism and permanent neurological and other damage associated with severe episodes of the disease.

Economists rate malaria among the top global priorities for spending on international aid. At the *Copenhagen Consensus* conference in May 2004, eight economists—three of them Nobel laureates—were given the hypothetical task to allocate US\$ 50 billion to meet some of the world's most pressing challenges. They allocated US\$ 13 billion for malaria prevention and treatment, spreading the funds across three strategies: making insecticide-treated mosquito nets available to an additional 60 million children under five years, providing preventive anti-malarial treatment to 90% of pregnant women and giving artemisinin-based combination therapy (ACT) to 280 million infected people annually with the objective of halving malaria prevalence by 2015. Together, these anti-malarial measures would deliver cumulative benefits of more than US\$ 400 billion, according to the report.

IV. RECENT HISTORY OF MALARIA PREVENTION AND CONTROL

During the early parts of the 20th century, malaria control played an important role in opening up tropical areas to economic investments, often plantations. In the United States and Europe, a variety of locally tested methods such as house screening, environmental management and treatment of cases gradually freed large areas of malaria. In the 1950s, the World Health Assembly mandated WHO to initiate a global malaria eradication programme, although it was acknowledged that it was uncertain whether eradication was feasible in sub-Saharan Africa. The campaign was based on large-scale spraying with DDT supplemented by other measures, such as treatment with chloroquine. As a result of the campaign malaria was eliminated from Europe, the Soviet Union, some countries in the Caribbean and the Middle East and greatly reduced in a large number of tropical countries in Asia and the Americas. By 1969 it was recognized that even outside Africa the biological and operational obstacles to eradication were much greater than had been thought and the global eradication programme was cancelled. Some countries, for example in the Indian sub-continent experienced a brutal resurgence of the disease, but in general the campaign had lasting benefits, partially in terms of areas that remained malaria-free, partially through the national capabilities that had been established. In tropical Africa, a number of pilot projects demonstrated that although malaria could be reduced it could not be eradicated because of the efficiency and abundance of the two main malaria vectors. For the next several decades, malaria attracted little interest, and scant resources were allocated by the international community to this problem.

Malaria did not reemerge as a major international health issue until the 1990 meeting of the World Health Assembly. There participants attributed the resurgent malaria situation to rapidly increased drug resistance, lack of clear strategy and shortage of financial resources. Development of an appropriate strategy and mobilization of resources to intensify effective intervention measures were recommended. The Amsterdam Ministerial Conference on Malaria of 1992 adopted a global strat-

egy that subsequently was endorsed by the UN General Assembly in 1993. This strategy recognized that the epidemiology of malaria is exceedingly variable and that its ecological, social and operational bases should be considered locally. The four fundamental elements of the strategy are:

1. Early diagnosis and prompt treatment
2. Selective use of preventive measures such as insecticide-treated mosquito nets and other mosquito control activities,
3. Prevention, early detection, and containment of epidemics
4. Strengthening local capacities in basic and applied research.

This strategy was well received by the international public health community and countries affected by malaria. Financial support, however, only materialized on a very limited scale, typically as funding for pilot projects covering a few districts or provinces in a country. Implementation was also constrained by prevailing uncertainty about the approach to the steady development of multi-drug resistance of *P. falciparum*—the strain that causes the most lethal form of malaria—and the limited evidence-base for the impact of insecticide-treated nets. But during the mid-1990s scientific research led to consensus about the most effective tools needed to fight malaria.

Despite mounting scientific evidence, implementation efforts stagnated through the 1990s. At a summit meeting in 1997, African heads of state unanimously passed a Declaration of Malaria Prevention and Control designed to promote African economic recovery and development. The Summit approved a comprehensive intervention plan for malaria and called upon all member states to take immediate and substantive action. UN agencies such as the World Bank, various governments and bilateral and multilateral agencies were urged to participate actively in the effort and mobilize additional resources to meet the challenge of malaria on the African Continent.

Also in 1997, key scientific and donor agencies convened in Dakar, Senegal to discuss collaborative efforts to address health problems in Africa. Malaria was selected as the initial focus. Out of this move, the Multilateral Initiative on Malaria (MIM) was created, as an alliance of organizations and individuals seeking to maximize the impact of scientific research on malaria in Africa. The creation of MIM was born out of several main needs. First, investment in research was low relative to the burden of disease. Second, malaria was recognized as a problem that required short-, medium- and long-term research priorities. Third, a gap existed between knowledge of the disease—its pathology and etiology—and its reduction in endemic countries, which led to the identification of another need: to strengthen research capacity in Africa. The MIM initiative has led to several effective partnerships between scientists from developed countries and their African counterparts.

In 1998, in the face of growing concern over malaria, a global partnership was formed under the auspices of the WHO, the United Nations Development Programme, the United Nations Children's Fund and the World Bank. It was called Roll Back Malaria (RBM), and its aim was, and is, to halve the burden of malaria throughout the world by 2010. RBM adopted the malaria control strategies that were accepted by the international community in the Amsterdam Ministerial Conference of 1992 under a strong banner of dynamic societal movement, coordinated action and partnership.

The RBM initiative has achieved notable momentum and consensus among the partners on malaria control. This initiative was instrumental in the development and formulation of country-led partnerships that included UN agencies, bilateral donors, various government sectors, civil societies, NGOs, the private sector, universities and research institutions. A number of malaria endemic countries have put together evidence-based strategic plans for implementation based on situation analysis of their respective ecological and epidemiological conditions, to address the burden of the disease within the context of health sector development. Despite the recognition and acceptance of the RBM goals, targets and strategy, funding constraints however, have restricted the effectiveness of individual countries' implementation efforts.

In 1999, following discussions between the WHO and the International Federation of Pharmaceutical Manufacturers Association, the representative body for the pharmaceutical industry, The Medicine for Malaria Venture (MMV) was established as a non-profit foundation, headquartered in Geneva. MMV uses the public-private partnership model, with funding from philanthropic organizations to facilitate discovery, development and delivery of new, affordable anti-malarial drugs. Since its inception, the MMV has played a significant role in streamlining drug research efforts by providing managerial and logistical support through active portfolio man-

agement, with a goal of increasing the success rate of potential anti-malarial therapies, resulting in an average of one drug discovery and development every five years. As of December 2003, the MMV had a total of 21 projects: 12 in the discovery phase and 9 in the development phase.

The African summit on Roll Back Malaria, held in Abuja, Nigeria in April 2000, reflected a convergence of political commitment and technical consensus on methods for dealing with the prevention and control of malaria. This convergence of political will was facilitated by the presence of high-level officials from African countries, as well as various bi- and multi-lateral agencies, resulting in the ratification of an action-oriented declaration. Furthermore, the summit endorsed the RBM movement and its objectives and set operational targets and milestones. Many of the major international donors that participated in the summit, including the World Bank and the African Development Bank, pledged increased commitment and resources. The World Bank alone pledged \$500 million.

Since the Abuja Summit, many African governments have demonstrated their commitment to anti-malarial intervention efforts by allocating human and financial resources and removing taxes and tariffs on mosquito nets.

The next major development was the establishment, in 2001 of the Global Fund to fight AIDS, TB and Malaria. Its objective is to support an array of national efforts designed to reduce the burdens of all three diseases. The program requires formal submission of a proposal by a country where malaria is endemic and evaluation by a panel of experts. Over the first four rounds of proposals the Global Fund has approved a total of \$1.8 billion dollars for malaria proposals with a duration of up to 5 years. This is the first time since the global eradication campaign that international funds commensurate with the size of the problem are becoming available. Although the funding volume is as yet far from covering the needs, it should be recognized that the Global Fund has made a significant difference and has motivated a number of malaria endemic countries to update their anti-malarial drug policies, to shift to effective combination therapies, and to scale up their interventions.

V. STRATEGIES FOR FIGHTING MALARIA

Science still has no magic bullet for malaria, and it is doubtful if such a single solution will ever exist. Malaria parasites are developing resistance to one drug after another, and many insecticides are no longer useful against mosquitoes transmitting the disease. Years of vaccine research have produced few hopeful candidates. Such research should be continued, but even with intensified efforts, an effective vaccine is, at best, 10–20 years away.

Nevertheless, effective strategies are available now for malaria treatment, prevention and control. Mosquito nets treated with insecticide reduce malaria transmission and child deaths. Prevention of malaria in pregnant women, through measures such as Intermittent Preventive Treatment and the use of insecticide-treated nets, results in improvement in maternal health, infant health and survival. Prompt access to treatment with effective up-to-date medicines, such as artemisinin-based combination therapies (ACTs), saves lives. If countries can apply these and other measures on a wide scale and monitor them, then the burden of malaria will be significantly reduced, as has already been demonstrated in a number of countries such as Brazil, Cambodia, Eritrea, Mexico, South Africa and Viet Nam.

Currently recommended malaria control strategies can be described as follows:

A. Prompt and effective treatment of malaria cases

Prompt and effective treatment is an apparently simple measure that aims to prevent the development of severe malaria and mortality. Nevertheless, it is a major challenge in countries with struggling health systems, because treatment must begin very early, generally within 24 hours after symptoms start. In areas with high transmission, the treatment (together with knowledge on the correct use) needs to be available in or near the home—availability at health facilities is often insufficient. Increasing worldwide levels of parasite resistance to chloroquine and sulfadoxine-pyrimethamine drugs are requiring artemisinin-based combination therapy in more and more countries; this is far more expensive than traditional monotherapy. Further, access to laboratory-based diagnosis (by microscopy or rapid diagnostic test) is becoming increasingly important, especially in areas where transmission is not so intense, to reduce the expenditure on newer treatments, to reduce the occurrence of side effects and to minimize drug pressure.

As a response to increasing levels of antimalarial resistance, WHO recommends that all countries experiencing resistance to conventional monotherapies, such as chloroquine, amodiaquine, or sulfadoxine-pyrimethamine, should use combination therapies, preferably those containing artemisinin derivatives (ACTs-Artemisinin-based Combination Therapies). As another step toward combating resistance, WHO

has also lowered the resistance-threshold for treatment policy from 25% to 15% as assessed by standard WHO protocols in children under 5 years of age, meaning that a more effective treatment should be adopted before 15% resistance to the old treatment is reached. I am including in my testimony, facts on ACTs, including the WHO policy recommendations for use of ACTs in treating drug-resistant malaria.

B. Prevention of malaria by reducing exposure to infective mosquito bites

A broad range of anti-mosquito measures is available. Those directed at reducing mosquito breeding are relatively site-specific and require a very high level of coverage to be effective. However, environmental management may have the advantage of sustainability and collateral benefits. In most tropical areas, where malaria remains as a major problem, two methods have the greatest and most universal potential: indoor residual spraying with insecticides and insecticide-treated mosquito nets and other materials. Even these interventions are not applicable in all situations, such as when dwellings have no sprayable surfaces or, sometimes, where people are highly mobile. Given a risk of malaria epidemics, vector control, usually indoor residual spraying with insecticides, may be the only effective option for prevention. In general, indoor residual spraying with insecticides is somewhat more demanding to organize than providing insecticide-treated mosquito nets. The latter intervention is much more readily adopted and maintained by communities and households and is therefore strongly promoted by international organizations, including WHO.

Under the Stockholm Convention on Persistent Organic Pollutants (POPs), the WHO addressed the use of DDT for disease vector control. The Stockholm Convention on POP permits the production and use of DDT strictly for disease vector control, under WHO recommendations and guidelines. I am including with my testimony, the WHO policy position on use of DDT under the Stockholm Convention, as well as, frequently asked questions about DDT use.

C. Prevention of malaria through chemotherapeutic measures

Several options are available, but some are already compromised by the development of drug resistance. In contemporary malaria control, one intervention is now strongly recommended: intermittent preventive treatment for pregnant women in areas of intense to moderate transmission of *Plasmodium falciparum*. This includes areas of stable malaria in sub-Saharan Africa. The most effective drug for intermittent preventive treatment is sulfadoxine-pyrimethamine. Using two doses of sulfadoxine-pyrimethamine in pregnancy is highly cost-effective in sub-Saharan Africa but could be expected to be effective only in few areas outside Africa. Little is known about the efficacy of drugs for preventing malaria in pregnancy among non-immune women and almost nothing about *P. vivax* in pregnancy. Both areas need further research.

D. Prevention and control of epidemics

Malaria epidemics can cause very high mortality rates; they occur, for example, in fringe areas of unstable transmission and when population movement brings non-immune people into areas with intense transmission. Prevention and control require good intersectoral surveillance (early warning and detection systems) and the rapid deployment of a mix of curative and anti-vector measures suited to the specific situation.

Box 1. The three core interventions to roll back malaria in tropical Africa

A substantial body of research has shown that combining three simple measures has the potential to greatly reduce malaria morbidity and mortality in nearly all malaria endemic areas in sub-Saharan Africa:

- promptly and effectively treating all cases of malaria;
- universal use of insecticide-treated nets, with priority for young children and pregnant women; and
- intermittent preventive treatment in pregnancy.

In addition, all malaria control programmes need to prevent and control epidemics, which incorporates surveillance, treatment and prevention.

New developments in malaria control

Rapid diagnostic tests (RDTs) detect malaria parasite antigens in the blood. The ones best validated are sensitive to *P. falciparum*, but tests sensitive to other parasites are on the market. These tests have some limitations, but they are very easy to use and have enormous potential for improving the quality of care and the

use of antimalarial drugs at the periphery of health services, especially when high-quality microscopy is not possible.

Artemisinin-based combination therapy (ACT) combines the rapid action, symptomatic relief and antigametocyte effect of artesunate and other artemisinin derivatives with the radical cure of longer-acting drugs. For falciparum malaria, parasites have not yet developed true resistance to the artemisinin compounds. Using these combinations may therefore help to prevent such resistance from developing and may retard the development of resistance to the synthetic partner drug. New combinations, which are expected to be cheaper and less complicated, are now being developed under the Medicines for Malaria Venture.

Home treatment for fever among children with prepackaged treatment courses to be available close to the home does not differ much from what has been practised for many years. Recent studies in Burkina Faso and Ethiopia have shown that, with adequate guidance and support, this can be a life-saving intervention. It is now being scaled up in Uganda and is starting to be implemented in several other national programmes.

Artemisinin compound suppositories are a safe, easy-to-use and highly effective treatment for severe malaria and for people who cannot swallow, whenever parenteral treatment cannot be safely applied. This intervention has considerable life-saving potential and it is already in use in some parts of southeastern Asia and sub-Saharan Africa.

Intermittent preventive treatment with sulfadoxine-pyrimethamine in pregnancy is highly effective in preventing low birth weight and anaemia. Controlled clinical trials indicate that intermittent preventive treatment has similar beneficial effects among infants, whose manifestations of malarial infection, mainly anaemia, are also silent. Large-scale trials of effectiveness started in 2003.

Long-lasting insecticidal nets are nets, where the insecticide has been bound to the fibres in such a way that it is not worn or washed off even by multiple washes. These can make prevention much simpler, when the insecticide effect lasts as long as the effective life of the net—about 4 years. Intense cooperation between WHO and industry has already led to lower prices for validated products and to the submission of competing products for validation by the WHO Pesticide Evaluation Scheme.

VI. PROGRESS IN IMPLEMENTATION

The 2003 Africa Malaria Report presents data on malaria control implementation in tropical Africa based on surveys carried out around year 2000.

Among the most notable findings of the report are:

- Malaria mortality probably increased from the 1980s to the 1990s, especially in eastern and southern Africa, probably mainly as a result of drug resistance. The current best estimate of malaria mortality in the world is one million deaths per year, of which 90% occur in Africa south of the Sahara;
- Median ITN coverage of children under five years found in the surveys was 2%; coverage of any kind of net was 15%;
- 40–50% of young children with fever were treated with an antimalarial drug within 24 hours of onset of symptoms. However, that antimalarial was probably in most cases chloroquine, the efficacy of which is in many countries not adequate;
- 13 of 44 African countries had abandoned chloroquine to use a more effective antimalarial treatment by 2003. Only two had adopted artemisinin-based combination treatment.

Since the publication of the Africa Malaria report in 2003,

- An additional 18 countries in Africa have adopted artemisinin-based combination therapy; 20 countries outside Africa also have an ACT policy. An additional 14 countries worldwide are in the process of changing their malaria treatment policy to ACT;
- A number of countries have greatly boosted their ITN coverage, by such measures as;
 - Regular, public, campaigns for free re-treatment (dipping) of nets with insecticide in areas of high net coverage
 - Combining ITN operations for under-five children with immunization campaigns;
- 14 countries in Africa have started implementing a strategy for control of malaria in pregnancy including intermittent preventive treatment;

- The GFATM allocations to malaria control now, after round 4, stand at 1,800,000 billion USD for projects with a duration of up to 5 years, or, approximately USD 400 million per year.

VII. PLANNING TO MEET THE GOAL OF REDUCING THE MALARIA BURDEN BY AT LEAST 50% BY 2010 COMPARED WITH 2000 AND THE MILLENNIUM DEVELOPMENT GOAL OF “HAVING HALTED AND BEGUN TO REVERSE” MALARIA INCIDENCE BY 2015

Development of a business plan for global malaria control

To be able to mobilize resources and commitment with unity of purpose and reach agreed goals and targets, it will be important to develop a global implementation plan. The process of developing it should serve as a framework for establishing the necessary consensus amongst stakeholders on planning and implementation of program activities and determination of required costs and funding gaps.

The following elements, will be essential:

1. A re-assessment of the global malaria burden and an assessment of current status of control
2. Scaling up interventions
3. Commodity management
4. Linkages to the development of health systems
5. Linkages to economic development and poverty reduction
6. Operational research to address strategically important questions
7. Renewal of interventions and the products on which they are based
8. Monitoring and evaluation
9. Costs and financing
10. Advocacy

1. A re-assessment of the global malaria burden and an assessment of current status of control

The malaria situation in Africa was thoroughly assessed as indicated in The Africa Malaria Report 2003. A re-assessment of the malaria burden outside Africa is on track, as WHO is preparing a World Malaria Report to be published by the end of 2004. This process needs to be supplemented with an assessment of global needs, and an assessment of the current status of control. It is particularly important to identify which areas and populations in areas with low or epidemic transmission need to be covered with insecticidal intervention. In some areas with low risk, full coverage of ITN or IRS is not cost-effective and should be replaced by strengthened surveillance combined with a capacity for rapid response.

2. Scaling up interventions

The collective and integrated use of interventions based on diagnosis and treatment, IPT during pregnancy, ITNs, IRS for epidemic prevention and control and anti-larval measures will result in significant impact. The level of impact depends not only on the level of coverage, but also on the optimal selection of combinations of interventions in accordance with local ecological and epidemiological characteristics. Much public health debate has centered around “absorption capacity”; practical experience indicates that this is an issue mainly in the early years of programme implementation, and that with adequate funding and good planning it is possible to scale up from coverage levels of a few % to over 80% in about 3–4 years. Good planning is required at national and district levels; it is contingent on local situation analyses, and needs to include information systems, training, human resource management, communication, community mobilization, demand creation and quality assurance. A crucial component, too often neglected, is logistics and supply chain management. In many countries, large quantities of nets, insecticides, artemisinin-based medicines and rapid diagnostic tests will need to be managed, and existing infrastructure may need to be upgraded.

Achieving high coverage with insecticide treated nets (ITNs) in populations living in areas of intense malaria transmission in Africa and elsewhere remains one of the main challenges to effective malaria control. There have been positive experiences with the promotion of insecticide treated nets (ITNs) based on various kinds commercial mechanisms and cost-sharing including social marketing. However, such approaches alone will not be sufficient. Much greater emphasis must be given to subsidized or free distribution of ITNs to vulnerable groups such as children under the age of five, pregnant women, and people living with HIV/AIDS. Experiences from a number of countries (such as Cambodia, Ghana, Eritrea, Malawi and Zambia) indicate that subsidized or free distribution of ITNs to vulnerable groups in rural

areas—in combination with other health promotion like an immunization campaign—is associated with high rates of use. Campaigns combining ITN distribution with measles immunization campaigns are now being planned in Togo, Niger and several other African countries.

Malaria epidemics and complex emergencies can greatly increase costs of operations and jeopardize the possibility of attaining impact. Experience has shown that it is important to maintain emergency funds and revolving emergency stocks. It is essential in the reporting on coverage and impact not to neglect populations affected by such emergencies, as these currently account for a large proportion of the world's malaria problems. A specific line of products for malaria control in complex emergencies, such as insecticide-treated tent materials, is under development by industry in cooperation with WHO and NGOs.

3. *Commodity management*

The core interventions are contingent on sufficient supplies of quality products, many of which are currently just becoming available, such as fixed dose combinations of ACTs and long-lasting insecticidal nets (LLINs). It is desirable from a viewpoint of sustainability to have all malaria commodities managed by national procurement and distribution systems, buying products fulfilling specifications, in a competitive global market. However, given the immature markets for some products, the rapidly increasing demands and the risk of sub-standard and counterfeit products, a certain degree of international intervention will be required, at least for some years. The actions required are:

- Forecasting of needs and demand at short, medium and long term
- Communication of forecasts to producers
- Cooperation with and among producers to improve quality
- “Soft contracts” supported by financial guarantees with producers for products requiring considerable lead time, such as ACTs
- Bulk procurement (especially for clusters of small countries with similar needs)
- Pre-qualification of products based on specifications, documentation and inspection of production sites
- Quality control of products at importation and at end-use point
- Combating fake and counterfeit products through international cooperation, law enforcement and mobilization of civil society.

In relation to ACTs, it has now been recommended to introduce a global subsidy “upstream” in the production and distribution chain. The purpose of such a mechanism would be to make ACTs available at a cost similar to that of chloroquine to end-users in all endemic countries through public and private channels.¹

4. *Linkages to the development of health systems and human resources*

The linkages of malaria control to health systems development is related to the following main issues:

Human resource development

Malaria control including high coverage of treatment as well as prevention is only possible when a national plan of action includes a substantial human resource development plan, which would typically comprise the following:

- Central level institutional development for management of human and financial resources as well as capacity for partnership, for example, with private, commercial sector, economic development projects; sub-contracting and information management; cross-programme links especially with HIV/AIDS, tuberculosis and maternity and child health.
- Development of capacity at district level for micro-planning, cross-programme links with immunization and filariasis and other programmes for ITN delivery, with antenatal care for IPT, with Integrated Management of Childhood Illness (IMCI), and with hospital services for delivery of treatment.
- Development of community-based services for prevention of treatment.

On the background of the general attrition of the public health workforce in many developing countries, the sustainable development of human resources presents the most formidable challenge of all. While training and supervision are necessary ele-

¹Institute of Medicine: *Saving Lives, Buying time: Economics of Malaria Drugs in an Age of Resistance*. National Institutes of Health, Washington D.C., 2004

ments, and should be addressed at global level by development of standardized training materials and tools, it will be necessary to take bold measures to maintain staff, probably by intervening to ensure attractive employment conditions by such measures as salary supplements. Such measures could be associated with risk of graft, wage inflation and stimulation of rent-seeking. They must be planned in a broad health system framework, to avoid depleting those branches of the health system which are not benefiting from substantial donor support.

B. Service delivery

Continuous high coverage service delivery is contingent on human resources, logistics, communication, infrastructure, program coordination, quality control and supervision. These elements may appear simple, but they are critical for the success of any programme, and precise planning is required to ensure allocation of necessary resources which are often underestimated. One of the important problematic coordination issues is related to the frequently conflicting demands for maintenance of fixed routine services and outreach campaigns. Such problems occur frequently in the context of polio and measles campaigns and in many countries, health services are learning to deal with them.

5. Linkages to economic development and poverty reduction

The systematic implementation of case management and prevention with adequate products should lead to transmission reduction to such an extent that malaria as an obstacle to investment will be substantially reduced. A number of caveats need to be observed in this connection. In some parts of Africa, a substantial reduction of morbidity and mortality for the local population may be attained, even while the level of risk to non-immune foreigners remains high enough to act as a deterrent. In such situations, the inclusion of additional or intensified measures aiming to reduce transmission should be planned inter-sectorally in the context of economic development, and the additional resources should be sought from investors outside the health sector. In some parts of the world, malaria control may open up certain areas to people who are likely to want to make quick profits from forestry, to the possible detriment of local people, the environment, and long-term development. Obviously, in such situations, there is a need for inter-sectoral and participatory development planning rather than absolute faith in the ability of malaria control by itself to solve economic problems.

Malaria control developed as a part of health systems development is normally an accompaniment to economic development, because the natural trend of health systems is to grow from centre to periphery in parallel with general social, economic, political and economic development. Such a vision of malaria control is consistent with the requirement for sustainability, but may be less satisfactory if malaria control is meant to be part of a poverty reduction strategy. However, for poverty reduction, it would again be best to demand that a broad development strategy for a given population group explores the possibility for including malaria control as a contribution to poverty reduction rather than positioning one specific disease control program as the motor of development.

6. Operational research to address strategically important questions

A number of questions, as indicated in the previous sections need to be answered by operational research. They are of crucial to be able to make progress in achieving high coverage with interventions without wastage of resources. A global business plan needs to make provisions for research to answer questions that need to be addressed at global level and provide a framework for the inclusion of operational research in national malaria control plans. Any operational research agenda needs to be updated frequently in response to emerging problems and new opportunities, especially those related to new tools. Currently, some of the most important issues for operational research are related to:

- The use of rapid diagnostic tests;
- Design of pharmaceutical management systems be to ensure that ACTs are not used after expiry date, but are always available at community level;
- Expansion of IPT beyond antenatal services;
- Distribution and maintenance of ITN through cooperation with immunization and reproductive health programmes;
- The role of larval control in African and Indian cities.

7. Renewal of interventions and the products on which they are based

The eventual blunting of any biocide used continually on a large scale is inevitable, despite the delaying power of various combination strategies. The main rea-

son for this is the development of resistance, but for vector control interventions, it is necessary to take into account also the real possibility of changed behaviour of mosquitoes. Even for some types of vaccines, it is possible that plasmodia could develop resistance. While combination strategies can delay the onset of resistance to individual substances, they will inevitably expose more substances at the same time. The only certain way to avoid setbacks caused by resistance of pathogens and vectors is to have new biocides in the pipeline to replace the ones that have been blunted.

One urgent research need is the identification of an antimalarial drug that is safe enough to be used for IPT in pregnancy (and possibly infancy), when SP is no longer effective because of resistance. The Medicine for Malaria Venture in Geneva is collaborating with scientists, industry, and international organizations and is expected to play a major role in ensuring the availability of affordable, effective antimalarials in the future. Currently, it has three novel ACTs and a synthetic artemisinin-like compound in the pipeline.

While the most dramatic setbacks in malaria control have been caused by the development of resistance to antimalarial drugs, there is now reason for optimism in relation to the antimalarial drug pipeline. In contrast, there is great uncertainty as regards insecticides, and consultation among industry, scientists and other partners is urgently needed to identify an appropriate strategy for development of new products. Radically new methods such as vaccines or genetically modified mosquitoes may also be included in the framework.

In relation to existing tools, there is still room for improvement. Industry and scientists are already working on novel long lasting net treatment techniques that could be used in the field and would be inexpensive. There is a need for improvement of rapid diagnostic tests, especially in terms of including more antigens to increase sensitivity. Some of the ACTs currently used, such as artesunate + amodiaquine, need to be developed as fixed-dose combinations that can receive regulatory approval. This is also the case for artemisinin derivative suppositories, which are potentially extremely useful for treatment of severe malaria at community level.

8. Monitoring and evaluation

The Africa Malaria Report 2003 gives an indication of the monitoring and evaluation systems that will be applied. The national 3-year sample surveys through Demographic Health Surveys and Multiple Indicator Cluster surveys provide data on childhood mortality and a platform to capture changing coverage, sources, compliance and timing of interventions, including those provided through formal and informal channels. This is now being supplemented by specific malaria control surveys, by in depth data from demographic surveillance sites in some countries, and by improving quality and use of routine health information system data.

In the context of the development of a global plan, it will be necessary to include concrete details about what indicators will be reported when, by whom, so that it is clear to all stakeholders how progress towards goals, objectives and targets will be gauged year by year and country by country.

9. Costs and financing

If coverage rates and benchmarks are agreed upon, then it is relatively simple, especially for tropical Africa, where the populations at risk are well defined, to calculate the total costs. However, these will not remain constant, and the following trends and issues need to be considered:

- Increasing urbanization will tend to decrease the malaria morbidity and mortality.
- Increasing AIDS burden will tend to increase severity of malaria, especially in urban populations with relatively low malaria immunity.
- Costs of commodities, especially antimalarial drugs (e.g. ACTs) are expected to decrease within a few years from approximately about US\$ 2.5 per adult dose to approximately about US\$ 1.2 per adult dose or less. Synthetic endoperoxides could make ACT-like combinations much cheaper, but it is also necessary to entertain the possibility that future antimalarials could be more expensive.
- Decreased malaria incidence will translate to decreased malaria hospitalizations, and may decrease the consumption of antimalarial drugs considerably, if specific diagnosis proves reliable and feasible and is widely adopted and accepted as a prerequisite to antimalarial treatment by providers and population. Under all circumstances, the feasibility of using rapid diagnostic tests (RDTs) will be of major influence in relation to treatment costs. The research

evidence for this is not yet available, and it is necessary to consider scenarios with and without RDTs in costing exercises.

- Although most commodity costs for novel products tend to go down with time, the need for replacement as resistance develops will mean that prices go up again. One of the purposes of international cooperation is to dampen such fluctuations.

On the basis of costings of all commodities and activities and a precise assessment of populations at risk and their exposure to various levels of malaria transmission, the annual costs of achieving 70% coverage of children under five by ITNs over a period of three years, and implementing IPT and implementing ACT universally in tropical Africa with a total population of 663 million have been calculated as follows:

	USD million
Treated nets for children & pregnant women	277
Preventive treatment for pregnant women	3
Treatment for severe malaria	3
Artemisinin-based combination therapy	1,164
Epidemics	137
Training	91
Community capacity and education	110
Infrastructure, institutions, operational research, supervision	163
Total	1,948

For malaria endemic countries outside Africa, the estimations will be more difficult, due to the difficulty of estimating the risk populations which need to be protected by given vector control measures. Furthermore, in many of these countries, the government malaria control budget is already substantial, and it is important to avoid the replacement of government funding by international funding.

The estimations of cost in the business plan should be complemented by a flexible financing plan. In the current phase, where there is broad international consensus that effective malaria control interventions must be scaled up rapidly to achieve impact, there is hardly any alternative to external financing as the main source of funding for malaria control. However, in the longer term, it is necessary, through health systems research, to explore how the existing motivation for paying out of pocket for individual malaria prevention and treatment (Africa Malaria Report 2003) can be channeled to full or partial payment for effective interventions, and whether the development of malaria control as part of public health could contribute to the development of health insurance schemes.

Currently, the dominant malaria control funding mechanism at international level is the Global Fund GFATM, which provides support for countries. GFATM mechanisms by themselves are not ideal for funding and securing external technical assistance needed by countries for implementation, monitoring and evaluation, nor for health system research and development. It is not part of GFATM's mission to finance upstream research for the development of new products. It is uncertain whether GFATM has the best mechanisms to meet the recommendations from the Institute of Medicine for upstream financing of ACTs.

10. Advocacy and Communications

A business plan must be accompanied by a communications and advocacy plan, of which a main purpose is to present the business plan as such, in particular its promises and its costs as well as the dimensions of the malaria problem and the collateral effects of the plan. It would be important to present the argument for the sustained and substantial, but slowly decreasing, resource inputs which will be needed at every level.

VIII. CONCLUSIONS

The strategies needed to fight malaria are clear. The challenge lies in making effective prevention and treatment available to the people who need them. Funding is now beginning to become available at a scale commensurate with the problem, but it is important to be clear about the need for increasing the volume to close to USD 2 billion per year for tropical Africa and to maintain the funding. A decisive factor in relation to increased international funding is the documentation of results and impact in countries.

Mr. TANCREDO. The Chairman will be back as soon as he casts a couple of votes.

Dr. Bate.

**STATEMENT OF ROGER BATE, PH.D., DIRECTOR, AFRICA
FIGHTING MALARIA**

Mr. BATE. Mr. Chairman, thank you for inviting me to testify on behalf of Africa Fighting Malaria on the current malaria situation in Africa.

Ninety years ago, 1 million Americans suffered from malaria, and a congressional Committee held hearings to discuss policy options. Eventually, and thankfully, malaria was eradicated from the United States by the early 1950s and other G-8 countries as well.

Today malaria kills, as we have already heard, Africa's children like flies. It would be the equivalent of loading seven Boeing 747s with children and crashing them to the ground every day. But, of course, malaria not only kills people, it keeps them poor, approximately, as we have heard, \$12 billion a year, 1 percent of GDP. Unfortunately, we also appear to be losing the war on malaria. Far from rolling the disease back, it has probably increased 10 percent in the past few years.

There are bright spots, however. Some African countries are enacting comprehensive malaria control programs which are grounded in the idea that success requires every tool that science has provided, much like the United States did to rid itself of malaria 50 years ago.

South Africa, where I lived for several years in the 1990s, uses low-level controlled indoor insecticide spraying and prompt treatment of malaria cases to keep malaria incidence low. The insecticide use I am describing here is vastly different from the widespread spraying from the backs of trucks or agricultural spraying from aircraft that we saw in the 1950s and 1960s. Indoor residual spraying has already been described and involves the application of a very small amount of insecticide on the interior walls and under the eaves of houses.

This is an important point because you are talking about ounces for malaria protection versus the many tons we used in agriculture. Environmental contamination is not caused by this comparatively minuscule use.

Policymakers, unfortunately, sometimes overlook that difference. In 1996, the South African Department of Health stopped using DDT and a terrible epidemic resulted. Seeing rates skyrocket, South Africa soon reversed course. With international approval, it reintroduced the use of DDT and introduced a new drug. Dr. Schapira just mentioned the artemisinin-based combination therapies. The combination of the insecticides and the new drugs caused cases to fall by almost 80 percent in nearly 18 months.

Zambia is probably a better example because it has malaria all year round and it is one of the poorest countries in Africa. But it, too, has enacted a program similar to that we have seen in South Africa. This program was started by a private mining company, initially covering 360,000 people, and it reduced malaria 50 percent in year one and further declines and remarkably zero deaths from year two onwards.

As a result, the Zambian Government, supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria, has agreed to fund nationwide indoor spraying programs. Combined with the use of bed nets and effective drugs, Zambia, too, will experience a precipitous decline in malaria cases at a relatively low cost.

Unfortunately, the U.S. Government's direct role in this, in the two most successful strategies of indoor residual spraying and effective drug treatments, is virtually zero.

Inexplicably, most international aid organizations resolutely refuse to fund comprehensive programs like those in South Africa and Zambia. One group, the Global Fund, is the only international public donor to provide even marginal purchasing of DDT and significant purchasing of these newer and effective drugs. A great market test for whether a drug will be available in the future is to buy it. Being new at it and less bureaucratic, it was more responsive to pressure from malaria specialists and demands of African nations themselves.

Despite the obvious benefits of programs such as these, by its own admission:

“USAID typically does not purchase drugs or medicines other than exceptional or emergency circumstances, and insecticide spraying is not a major focus of any of our programs.”

As we have heard, the mainstay of USAID programs is bed nets, but even here it is uncertain how many are being bought and what effect they have. There is a significant lack of transparency as to how money is being spent and this needs to change. I welcome an initiative by Senators Gregg and Feingold to ask the General Accounting Office to investigate USAID's malaria activities.

In the successful programs I have described in South Africa and Zambia, within a season or two, massive reductions in malaria have been witnessed. Yet for the programs funded by numerous aid agencies we see few outcome measurements. We just hear how many bed nets have been distributed.

There is little talk of mortality-morbidity changes, how much malaria has changed. Do we even know how many people regularly sleep under the nets? Imagine a hot, humid August night in Washington, DC, with your air conditioner not working and having to sleep under a stifling bed net. Although I know the many risks of malaria and have been in many malarial countries, there have been times where I simply couldn't sleep under a bed net, it was just too hot. Therefore, there often is significant resistance to net use. I am not opposed to nets at all. They are very, very useful and they always will have their place.

But coming back to the results, malaria is not like AIDS where you can see results rapidly. And it simply isn't good enough, in my opinion, for agencies to claim that bed nets are being delivered, in-

frastructure is on its way to being built, and data is not there. We need to see the results.

When global eradication of malaria was tried 40 years ago, massive reductions in transmission were made, but by overrelying on DDT, success was far from total. Today the key history lesson is lost. The lesson is not that DDT should not be used, it is that overrelying on one tool is folly.

We have heard a lot of talk today about multimodality delivery systems, but the real effect is that we are overrelying today as we did in the past. Today we are overrelying on bed nets.

To win against malaria, agencies need to find interventions that work, which is the example of South Africa and Zambia that show using bed nets, yes, but in many cases, and more importantly, indoor residual spraying with insecticides, and the best available drugs.

Unfortunately to say that, if accountability and transparency and—most importantly—results are not delivered and delivered soon, U.S. funding for these programs should be reallocated to agencies that have a better chance for improving health. Too many children die from this disease for such failure to continue.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Bate follows:]

PREPARED STATEMENT OF ROGER BATE, PH.D., DIRECTOR, AFRICA FIGHTING MALARIA

Mr. Chairman, Congressman Payne, thank you for inviting me to testify on behalf of Africa Fighting Malaria on the current malaria situation in Africa.

Ninety years ago a Congressional Committee held a hearing on malaria, but its focus was slightly different. It concentrated on combating malaria in the United States. It was the topic near and dear to the hearts of some of the Committee Members, not only because their constituents suffered from malaria, but some of the Committee Members had as well.

As late as 1940 at least a million people¹ in the United States experienced the body shaking chills, fevers, and sweats of malaria. However, using federal and private funding the Rockefeller Foundation, the Tennessee Valley Authority, and the United States Public Health Service enacted comprehensive programs to counter the conditions under which malaria flourished in the US. Through a combination of treating infected people with effective drugs, larviciding areas where mosquitoes bred, and the spraying outdoors and the interiors of houses with the insecticide DDT, these groups managed to eradicate malaria from the United States by the early 1950's.

Today no Member of this Committee will have contracted malaria in the United States, but some of you may have contracted it abroad. While we are now malaria free in the United States, other areas of the world are not so lucky. Malaria is the biggest global killer of children. Sub-Saharan Africa in particular bears the brunt of the malaria death toll of 1–2 million people a year, 90% of whom are pregnant women or children under the age of 5. That is about the population size of Maine, dying every year. As Dr Wen Kilama, Chairman of the Malaria Foundation International puts it, "The malaria epidemic is like loading up seven Boeing 747 airliners each day, then deliberately crashing them into Mt. Kilimanjaro."

Malaria not only slaughters African children. It also perpetuates the cycle of poverty, much as malaria kept the American South poor until its eradication.² The

¹Ackerknecht, *Erwin, Malaria in the Upper Mississippi Valley, 1760–1900*, New York: Arno Press (1977).

²In 1921 a malaria worker attested to malaria's power in squelching development in the South:

"In a malaria zone there is nothing that happens or occurs in that zone which can equal malaria in cost or economic loss. . . . In every instance a malaria survey . . . shows a high ratio of poverty. I don't mean by poverty that they simply starve and can't live. I mean poverty in efficiency, poverty in making money, poverty in thrift, poverty in interest, poverty in progress, poverty in all the factors going to make up efficiency—that is what I mean. On the other hand, in Georgia wherever there is a low ratio of malaria there is a low ratio of poverty. The minute that your ratio begins to change and your

economist Jeffrey Sachs conservatively estimates that malaria costs Africa 1.2% of its GDP, about \$12 billion, every year (the equivalent for the US would be about \$135 billion dollars a year). African GDP is a third lower than otherwise would have been the case if malaria had been eradicated 30 years ago³

ROLL BACK MALARIA

According to World Health Organisation (WHO) reports, malaria rates have increased about 10% in the past few years. This increase occurs at a time when the twelve year global initiative to halve rates of malaria is approaching its half way point. The US is the main funder of the Roll Back Malaria initiative and it is failing.

THE SOUTH AFRICA EXPERIENCE

Some countries in Africa are fortunate though. Their governments are enacting comprehensive malaria control programs much like those used to eradicate malaria from the United States. These successful programs are grounded in the idea that effective malaria control employs every tool that science has provided.

South Africa has had such a program for over 50 years. South Africa depends upon a combination of low-level, controlled indoor insecticide use and prompt treatment of malaria cases to keep malaria incidence low (bed nets and reducing mosquito breeding sources are also employed in a limited way).

The insecticide use I'm describing here is vastly different from the widespread spraying from the backs of trucks or agricultural spraying from aircraft that we saw in the 1950s and 1960s. "Indoor residual spraying" (IRS) involves the application of a small amount of insecticide on the interior walls and under the eaves of a house. This method can use three different types of insecticides to successfully control mosquitoes.

In 1996 the Department of Health of South Africa decided to replace the insecticide it had used for 50 years, DDT, with synthetic pyrethroid insecticides. However, largely because agriculture uses synthetic pyrethroid insecticides, insecticide resistance soon became a problem. What followed was one of the worst malaria epidemics in the country's history. Malaria cases rose from around 6000 in 1995 to over 60,000 in 2000.⁴

SOUTH AFRICA GOES "COMPREHENSIVE": DDT + EFFECTIVE DRUGS

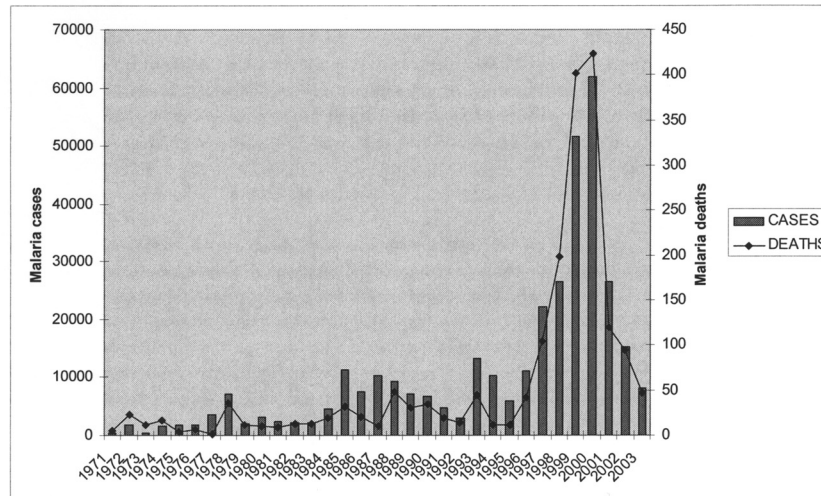
Led by the South African Government, the international community agreed in 2000 that DDT could still be used for disease control⁵. South Africa reintroduced DDT to malaria control in KwaZulu Natal Province, the province worst hit by the epidemic. Additionally in 2001, South Africa introduced a new drug Coartem, an artemisinin based combination therapy, to treat malaria patients. *The combination of insecticides and drugs caused malaria cases to fall by almost 80% by the end of 2001.*

malaria ratio comes down, your economic conditions improve immediately; you begin to get better conditions; the mind is more acute, more active, and there is more natural willingness to work. The children's attendance at schools improve and you begin to get good results in their education." In 1940 Ackerknecht estimates that the direct cost of malaria in the United States was much as \$51,000,000, whereas the overall economic impact ranged at high as \$500,000,000 a year.

³ <http://www.usaid.gov/our-work/global-health/id/malaria/publications/docs/abuja.pdf>

⁴ South African Department of Health, *National Malaria Update* (SA Dept of Health, 2003, Pretoria)

⁵ <http://www.icps.it/english/bollettino/psn00/000401.htm>

Chart 1: Malaria Cases and Deaths, South Africa, 1971–2003⁶

South Africa is not the only country with a successful comprehensive malaria control program.

MALARIA CONTROL NOT ONLY FOR RICH NATIONS: EMERGING SUCCESS IN ZAMBIA

In the early 1980s Zambia, one of the poorest countries in Africa, discontinued its insecticide spraying program, due largely to financial constraints. As a result the incidence of malaria increased from approximately 120 cases/1000 population in the late 1970s to over 330/1000 in the late 1990s.

But today Zambia has once again developed a successful malaria control program. In 2000, a privately funded malaria control program (based primarily on insecticide spraying) in the Zambian Copperbelt began using DDT. It protects a population of approximately 360,000 at a cost of \$6 per household (where there are approximately 11 residents per house)⁷. After just one spraying season, malaria cases declined by 50%.⁸ Today case rates are down 80% since the inception of the program, with mortality rates reduced even further since the introduction of newer and better drugs. The success of this program influenced national malaria control policy such that Zambia has now implemented DDT and pyrethroid IRS programs in other parts of the country with equally good results. As a result of the successes seen there, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, has agreed to fund nationwide indoor spraying programs in Zambia. Combined with the use of insecticide treated nets placed over mats or beds where children sleep, and effective drugs, Zambia too is experiencing a precipitous decline in malaria cases. The Copperbelt insecticide based program is not only highly successful, but cost effective as well.

In spite of these successes the US government's involvement in the two most successful strategies, indoor spraying and effective drugs, has been very limited. Specifically, The United States Agency for International Development (USAID) recently increased its financial commitment to malaria control in Zambia and currently contributes around US \$4m to the malaria control program. However it is not clear how these funds are being utilized.

AID DEPENDENT COUNTRIES NOT SO FORTUNATE

Not all countries have been as fortunate as these however. While South Africa is relatively wealthy and can afford to fund its own programs and Zambia benefited from private interest in its mining sector, most African countries rely on inter-

⁶South African Department of Health, *National Malaria Update* (SA Dept of Health, 2003, Pretoria)

⁷Sharp et al. (2002) "Malaria control by residual insecticide spraying in Chingola and Chililabombwe, Copperbelt Province, Zambia" *Tropical Medicine and International Health*, 7, no 9: 732–36

⁸ibid..

from private interest in its mining sector, most African countries rely on international public donors to support their malaria control programs. Zambia was fortunate in that a private company's project showed how successful a multi pronged strategy that includes the use of IRS could be for the country.

In Uganda, the Ministry of Health has declared its intention to use DDT as one of a range of different interventions against the disease. During the 1950s and 60s Uganda used DDT very successfully and reduced parasite prevalence among all age groups from 22.7% to just 0.5%⁹. Debate is ongoing among the scientific and medical community in Kenya as to whether or not to reintroduce IRS programs using DDT. The US government should support the decisions made by the scientists and experts in both these countries to use the best available tools to fight malaria. It is incumbent on the US to provide the leadership for other donors, as it has done with respect to HIV/AIDS, and support programs that will save as many lives as possible.

Inexplicably, most international aid organizations resolutely refuse to fund comprehensive malaria control programs like those in South Africa and Zambia. Responding to pressure from malaria specialists and critical media coverage of its previous funding allocation, The Global Fund to Fight HIV/AIDS, Malaria and Tuberculosis is the only international public donor to provide even marginal support for DDT and effective drugs to combat malaria.

Other international aid agencies rarely fund indoor insecticide spraying programs, especially those that use DDT. Aid agencies have also knowingly and repeatedly purchased ineffective drugs for malaria treatment or not purchased any drugs at all¹⁰. These refusals are often directly counter to the wishes of the malarial countries themselves.

USAID: BENIGN OR MALIGN INFLUENCE?

Regardless of its glorious past in malaria control, and the recent efforts to persuade Congress of the importance to combat malaria, I am sad to say that one offender is USAID. Not only does USAID resist funding some of the most effective interventions, but it wields its great influence throughout the international public health community to discourage support of these interventions by the Global Fund, the United Nations, and by individual country malaria programs who know that USAID is their main donor.

Despite the obvious benefits of comprehensive malaria control programs, by its own admission, "USAID typically does not purchase drugs or medicines other than in exceptional or emergency circumstances for any of our programs" and "IRS is not a major focus of our programs." Since the President's AIDS plan will require the massive purchase of drugs, and USAID happily purchases condoms, bednets, female condoms, bleach kits, safe drug injection propaganda, it seems a bit disingenuous for USAID to claim that drugs to treat disease are somehow out of bounds, especially when it funds vaccine research.

What then is the major focus of USAID's malaria program?

LACK OF USAID TRANSPARENCY AND ACCOUNTABILITY

In 2003, USAID received a Congressional allocation of \$65 million dollars. As USAID's money does not, by its own admission, go to the purchase of antimalarial drugs, or to funding indoor spraying, you would hope that some goes to the purchase and distribution of bednets. Some does, about \$ 4.2 million of it, but USAID's net distribution program often flies into the face of economic realities in African countries, by charging for nets. Most people in Africa cannot afford to purchase bednets even at cost. Thus most countries in Africa try to heavily subsidize the purchase of the nets or distribute them for free.

WHAT IS USAID BUYING?

Still this is only \$4.2 million out of \$65 million that goes to this program for the prevention of malarial infection. Of the \$65 million, USAID asserts that it spends 28% on the prevention of infection. \$4.2 million is a bit short of 28% of \$65 million so where does the rest of the money go? It apparently goes to the contractors to whom USAID distributes money to address these problems at the country level (presumably for education, distribution and capacity building). How do these contractors

⁹WHO (1971) "Official Records of the World Health Organisation No 190. Appendix 14, The Place of DDT in Operations against Malaria and other Vector-Borne Diseases" WHO, Geneva. p 179

¹⁰Attaran et al, WHO, The Global Fund and medical malpractice in malaria treatment, The Lancet, vol 363, 17th January 2004

actually spend the money? USAID apparently has no idea. When AFM advisors asked how the country contractors spend the money, the USAID office in Washington said they did not have access to that information in Washington. When asked how that information could be obtained, USAID did not even bother to reply¹¹.

US NATIONAL INTEREST IN EFFECTIVE MALARIA PROGRAMS

Congress needs to spend money on combating malaria in Africa, but it also needs to know how that money is spent so that Congress is assured that that money is being effectively utilized. Because as sufficiently compelling as the humanitarian reasons are, malaria in Africa also affects the United States' national interests.

First, U.S. Marines' experience a year ago in Liberia attests (22% contracted malaria), US troops are at a distinct disadvantage when entering a combat zone that is also a malarial area. Malaria posed a tremendous challenge to the troops in the Pacific Theater during World War II and soldiers in Vietnam, and Liberia shows that little has changed since then. If the troops had taken their antimalarial drugs there would have been fewer cases, but controlling malaria will make peacekeeping missions, perhaps into places like Sudan, less hazardous.

Second, like AIDS with which malaria is often found in deadly tandem¹², malaria is a destabilizing disease. By sapping the strength of adults, by compromising the educational development of school-aged children, and by killing young children, malaria severely retards the economic development of African countries, creating poverty and despair in its wake, and countries beset by poverty and despair are more prone to political instability than those that are not.

Finally, while no Member of this Subcommittee has caught malaria in the United States, that may change in the future. Malaria cases in the U.S. have primarily been imported in recent decades, but last year, an outbreak in Florida could not be traced to any traveler. This disturbing incident suggests that the U.S. could be on its way to welcoming this deadly disease back to its homeland.

In the past 15 years there has been an increasing number of locally transmitted malaria outbreaks in the United States.¹³ The outbreaks have been tiny and localized, but to epidemiologists they have been significant for two reasons: they show that endemic malaria is still a possibility in the United States, and, unlike outbreaks previous to 1990, and the last traces of endemic malaria in the United States in the late 1940's, these outbreaks aren't occurring in rural areas, but in heavily populated urban/suburban ones.¹⁴

A study from Minnesota indicates that increasing immigration from malarial countries and international travel and trade are changing the status of malaria in the United States. When analyzing cases of imported malaria in Minnesota over a decade, the study noted two significant trends: an increase in malaria during that time and; change in the preponderance of travel cases (cases where people contract malaria while abroad but don't express the symptoms until they return home) to immigrant cases.¹⁵

Unlike travel cases where symptoms almost always appear, some immigrants have active, transmittable malaria—if bitten by an *Anopheles* (malarial) mosquito the malaria could be spread to another person—but they do not express any symptoms.¹⁶ If the study hadn't actively been screening for malaria, these cases never would have been detected, even though these people would be carriers of malaria.

Mosquito borne disease will continue to threaten the United States. The US simply cannot close its borders to all international trade, travel, and immigration and it is through such routes that new vectors and new diseases, such as West Nile

¹¹ Previously AFM has filed Freedom of Information Act requests to obtain information from USAID and may have to do so again.

¹² Immuno-compromised adults are more likely to contract and die from malaria than adults without AIDS. Moreover, recent studies have shown that mothers with AIDS who have placental malaria have a higher risk of transmitting AIDS to their unborn children.

¹³ Jane Zucker, "Changing Patterns of Autochthonous Malaria Transmission in the United States: A Review of Recent Outbreaks." *Emerging Infectious Disease* 2, no. 1 (January-March 1996): 37–43.

¹⁴ The most recent outbreak of locally transmitted malaria occurred in West Palm Beach in 2003, with 8 cases. The incident previous to that occurred in Loudon County, Virginia with 3 cases in 1998. Outbreaks also occurred in NJ, NY, and Texas.

¹⁵ The Changing Epidemiology of Malaria in Minnesota." *Emerging Infectious Disease* 7, no. 6 (Nov.-Dec. 2001): 993–995.

¹⁶ The number of cases increased from 5 in 1988 to 76 in 1998. Out of the 76 cases of malaria in 1998, 11 of those cases fell into the symptomless category. Most of the malarial sufferers were refugees from malaria, out of the 11 non expressed cases, 10 were primary refugees. p. 994. As Minnesota once had endemic malaria it is not inconceivable that locally transmitted cases of malaria could also occur there as well.

Virus, have made their way here, and it is the way that old diseases, such as malaria, will re-establish themselves here.

The best way to prevent malaria from threatening the US interests both at home and abroad is to combat malaria where it is found by helping to fund effective, comprehensive malarial control programs. To date, except for the money that it has given to the Global Fund, there is no evidence that the United States does that effectively.

Africa Fighting Malaria recommends that the United States does the following:

- 1) USAID should increase its accountability. If USAID funds a program be it national or local or provides advice, commodities or anything else to a program, we suggest an outcome evaluation of that program. Moreover, outcome indicators MUST include reduced morbidity/mortality from malaria, NOT inputs like the number of bednets distributed. With bednet programs, USAID ought to be measuring the malaria incidence among households where it has distributed bed nets.
- 2) USAID should increase its transparency. This is a much shorter-term demand than #1. Transparency would be aided by knowing exactly how the \$65 million has been spent in every country. This information needs to be maintained and updated regularly on an accessible web site for the international public health community to scrutinize¹⁷. This disease is killing too many children every year not to provide this level of accountability.
- 3) USAID should change its programmatic approach. USAID should fund comprehensive programs, exactly modeling its AIDS policy, and learning from the successful approach undertaken in Zambia. This should mirror the AIDS program, where we use every available tool, prevention with ABC (Abstinence, Be faithful, use Condoms), and treatment with the latest and best drugs. To willfully not use one of the best methods to prevent the spread of the disease (insecticide spraying) and buy ineffective drugs or none at all is unacceptable.
- 4) USAID should use its substantial influence to aggressively encourage these same measures in 1, 2, and 3 throughout the world. For #1, USAID should be pushing appropriate indicators on every host country program, on Roll Back Malaria, WHO and especially, the Demographic Health Survey that takes place regularly. For #2, USAID should demand that recipient nations and private sector groups have perfect and down-to-the-last-dollar transparency about their programs if they want to get even a small amount of help with that program from USAID. And for #3, USAID must stop intimidating countries and actively promote insecticide spraying (including with DDT) and effective drug treatment.

Mr. TANCREDO. May I ask, just in response to the very last question, what are those agencies?

Mr. BATE. Well, under pressure from malaria specialists in African countries, the Global Fund in the last 6 to 8 months in particular—and probably moving in that direction beforehand—has, as I said before, started funding the use of DDT spraying and has increased the purchase of these drugs. As I said, the best market test for a drug is to actually go out and buy it. I would say that they are an agency that has improved because they are perhaps less bureaucratic and more nimble. Whereas some of the other agencies are exhibiting more inertia at least.

Mr. TANCREDO. I guess we all can recognize, perhaps, the kind of reluctance that develops. Inertia is certainly a good way to describe it in terms of use of other modalities, DDT in particular.

To the best of your knowledge, either one of you, is there, in fact, any other chemical that can be used beside DDT? Just because it presents an obstacle that is, I think, unfortunate because of the name and just because of what people think about what has hap-

¹⁷To date, there is no system in place for tracking international or national expenditure on malaria control.

pened in the past, can we overcome that with other kinds of chemical applications? Anybody?

Mr. BATE. There are alternatives. Those alternatives are being used. They should be used in such circumstances.

One of the advantages of DDT, however, is its persistence. The reason it caused the problem when used in the environment before was because of its persistence. That is extremely useful where you have year-round malaria because you only have to spray it once a year on the wall.

So, yes, there are alternatives, but often they are less cost-effective.

Dr. SHAPIRA. Yes, there are a total of 12 insecticides that can be used for interior residual spraying. DDT is the one that is cheapest but DDT is terribly bulky. You need nearly a pound for each African house and transport is a big problem. Then, DDT can actually be more expensive than some of the more modern insecticides.

And then it has some disadvantages. People sometimes don't tolerate them. So DDT is not the only one. What is very important is not to lose DDT from the portfolio because it is the only one in its class called organochlorides, and we have big resistance problems with insecticides.

So it is not that we need a terrible lot of DDT around the world. The country using most of the DDT is, without any comparison, India at the moment; and they should start taking their DDT resistance more seriously and think about changing. But we need—we cannot afford to lose DDT from the portfolio. And the persistence, it is true it is an advantage that it has.

Mr. BATE. If I can just jump in there. I think that is absolutely true. I concur entirely. But the only thing I would say is that it is incumbent on the agencies around the world to actually buy it, if you want it to continue to be used, because if it isn't bought, then the market will dictate, which is the reason only the Indian Government and the Chinese Government and perhaps the Russian Federation actually produce it.

Mr. ROYCE [presiding]. Let me ask you, Dr. Bate, a question. In your testimony, you allege that aid agencies have knowingly and repeatedly purchased ineffective drugs for malaria treatment. I was going to ask, which agencies are you referring to, and what drugs would you consider ineffective, and why do you think that they are ineffective in this way? Why do you think that aid agencies have conducted themselves in that way?

Mr. BATE. Chloroquine and sulfadoxine-pyrimethamine are the two drugs in question that have been inappropriately purchased in the past.

I sympathize sometimes with the aid agencies because African countries themselves have considerable inertia to change from one drug to another. But there is no doubt that in some instances you are talking about countries, I think, like Ethiopia. Off the top of my head, I think chloroquine resistance rises up to about 88 percent there. There are alternatives that should be used which are far more effective, will knock parasites out of the bloodstream faster, get people back to work and protect more people. So that is what I was referring to in terms of drugs that should be purchased. Chloroquine and the SP are the drugs that were ineffectual.

All of the agencies are guilty, but it is understandable to a certain extent. I would say that the Global Fund—in answer to a previous comment—is the one that is changing fastest in terms of moving to those new drugs. I think, because of pressure from within the malaria community and from some of the African countries, that it is moving across in that way.

Mr. ROYCE. And what steps do you think could be made on African Governments to get them to adjust there?

Mr. BATE. Well, I think a question that you actually raised yourself earlier. One of the biggest problems in many African countries is, there are actually taxes and tariffs on bed nets, insecticides and drugs as they enter the countries. It would be effective to criticize those kind of taxation policies.

In general, on drugs, and in particular on the artemisinin drugs, I think African countries want to buy things that work. But education programs are one of the things that USAID does do well in terms of on the ground. It provides expert support, and that is one of the things I am sure they will do.

Mr. ROYCE. I will go over to Dr. Schapira, because I started also my testimony with raising the concern about Equatorial Guinea and the incredible instance of malaria in that country, and with the observation that only 1 percent of the budget of revenues that come into that country, largely from oil royalties, ends up going for the purpose of public health. As you know, from some of the stories that appear in the papers, vast sums, a very large percentage, ends up benefiting members of the family connected with the Government.

I was going to ask you, is it problematic that a number of African Governments spend so little money on public health? Can you tell us what steps could be taken to push African Governments to spend more on public health? There are a number that are exemplary in this area. But we also have others, like Equatorial Guinea, that frankly, it is hard to believe when you look at the numbers; and I thought I would give you an opportunity, Dr. Schapira, to speak to that issue.

Dr. SCHAPIRA. Thank you very much. That was a tough one and it falls outside malaria. It is about accountability, I think, of Governments, for what they actually do with their revenues all together. Why don't they spend enough on health and social services even when they have substantial revenues?

I think we need to go along the avenue that WHO started in Dr. Brundtland's time of holding Governments accountable for how well they are doing in traditional services, and publish the data in the *World Health Reports*. I don't know if you remember—I think it was the *World Health Report 2000*. It led to an outcry, indignation among many Governments. And why did it cause an outcry? Because they were ashamed, they were exposed. And I think that is what needs to be done. It is the international community together that has to demand from U.N. organizations: Publish these data, put effort into that, invest in getting these data out. Then Governments should be held to account.

Mr. ROYCE. I thank you, Dr. Schapira.

We are going to go to Mr. Payne of New Jersey, the Ranking Member of this Subcommittee, for his questions.

Mr. PAYNE. Thank you very much. I apologize for missing your testimony.

But I wonder, Dr. Schapira, if this whole question of DDT and the fact that we know that years ago there was the ban, which actually is going in worldwide, and the netting; how do you feel about the use of the insecticide in the whole area, fighting malaria?

Dr. SCHAPIRA. I think one could try to say, in general, in the areas where malaria still exists, we need insecticides to fight it. Environmental measures sound very good, but in an environment where these measures could do the job, they have largely done the job. Malaria is still largely in areas where you need to do more aggressive things, so you need to use insecticides.

Now, how can you use insecticides? The main methods are interior residual spraying and insecticide-treated nets. Maybe roughly, let's say, 50 percent of countries will need to use nets in some areas, spraying in some areas, nets probably in the furthestmost areas.

Twenty-five percent of countries, largely including a number of African flat countries with not so many epidemics, really should not use spraying at all. They should concentrate on nets, do one thing and do it well, with complete coverage.

And then there are a few countries in Asia, especially where there is lots of highland malaria, where they could probably just as well concentrate on improving their spraying operations.

Among the insecticides that we need, DDT is very valuable, but it is not the only one for interior residual spraying. In most places, you can do indoor residual spraying perfectly well without DDT.

But it is a valuable insecticide. The important thing is to maintain this in the portfolio. That is why WHO put such a big effort into the Stockholm Convention, which has come into force this year, which bans the persistent organic pollutants, including DDT, but makes an exemption for DDT, which is allowed to be used for public health use according to WHO guidelines.

Mr. PAYNE. Let me ask either one of you, what is the prospect of developing even longer-lasting insecticide-treated netting? Is there any research going on now, Dr. Bate or Dr. Schapira?

Dr. SCHAPIRA. Yes. This is a field which is growing amazingly well. Until 1 year ago, we had only one kind of long life-lasting insecticide-treated netting. And new technology was approved by WHO last year, so we now have two brands which represent different kinds of technologies.

More technologies are underway. Very excitingly, it is a technology which allows you to mix the insecticide with a kind of glue so that you can take this product out to the village, where they may already have a lot of nets, and get these nets dipped in this mixture and then they will be long-lasting. It is not there yet, but the development efforts are going very well.

Mr. PAYNE. Just in general about the nets, are they distributed by international aid organizations? Are they available? It seems like it is something that, if it is so important and it can prevent—is this a priority of the aid agencies, and do they simply make it available everywhere in Africa?

Dr. SCHAPIRA. Yes. I think since the discovery about 1996 of the enormous efficacy of the insecticide-treated nets, all the players in

this field have been trying a little bit of everything: Social marketing, ordinary commercialization, free distribution and so on and so forth.

It has been shown that all these things work but the scale-up of coverage of vulnerable groups is going too slowly. So what we have learned now is that we must put more effort into the free distribution of nets specifically for the vulnerable groups—pregnant women, young children. And thank you, sir, for mentioning the AIDS patients, who are also vulnerable. They should have it free.

At the same time, the creation of markets, commercial channels, is enormously viable, enormously valuable, so that shouldn't be neglected; and that is, of course, where USAID has done particularly good efforts.

Mr. PAYNE. My final question is, could you just tell us what countries may have the best anti-malaria program in that country? We know, for example, with HIV/AIDS, Uganda came to the fore when they started to concentrate on their pandemic.

Many other countries have not been as successful, like Botswana. Even though the will is there, other countries have been unaffected—I mean, less affected where it isn't there in large numbers. Have you rated and studied and had best practices replicated?

Dr. SCHAPIRA. Yes. Uganda is doing very well. Eritrea is doing extremely well. What can I say? The kind of Government they have in Eritrea is useful for malaria control because it is extremely well organized. They are really having very good results. And Botswana, fortunately, is doing very well and I would say that Zambia is also doing a good job.

And it is going to be very interesting to see what will happen in Togo which, as the first country in Africa, is going to try to reach the full population with free distribution of insecticide-treated nets in one goal combined with this campaign. And in WHO, we are paying a lot of attention to this. We think it is going to show the way home.

Mr. PAYNE. Well, thank you very much. I know that, as a matter of fact, Eritrea, although it has been getting some bad publicity, has done a number of things in attempting—actually, the Government seems to put its interest in the people; and in a number of instances, of course, being one of the poorest countries in Africa, they have a very difficult time.

Just several weeks ago I met with the President of Eritrea and what he was laying out is music to my ears. If other rich—very few countries in Africa are rich financially; they have rich resources. Of course, as we know, Africa makes the world rich, and Africa remains poor. But I don't know where the world would be without Africa. It wouldn't be as wealthy as they are in places.

But that is another day, another subject, another time.

But I would just like to say that there are some countries that are trying to concentrate on, for example, the new Chadian oil find with the agreement with the World Bank that they have four categories—education, health, infrastructure, et cetera—that the money must go to, given from a contract with the World Bank to the Government, will go to those areas. I mean, we have to monitor it.

But I think we ought to also—as we look at the examples brought out by the Chairman, there are countries that are struggling, have very little resources, attempting to do the best they can with it.

So I appreciate the work of both of you very much. Thank you very much.

Mr. ROYCE. We also appreciate you traveling, Dr. Schapira, all the way here to the United States to testify here today. And Dr. Bate, we appreciate your testimony as well.

And so thank you so much. And with that said, our hearing is adjourned.

[Whereupon, at 3:45 p.m., the Subcommittee was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE HEARING RECORD

PREPARED STATEMENT OF THE HONORABLE GREGORY W. MEEKS, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF NEW YORK

Thank you Mr. Chairman for calling this hearing. While we often hear of the devastation that the AIDS epidemic has caused on the continent of Africa, we hear much less about two other diseases that have proved to be equally as deadly—malaria and tuberculosis.

3,000 people die from malaria each day in Sub-Saharan Africa. Most of them are children.

1.5 million people in sub-Saharan Africa are infected with TB and because people with HIV are 50 times more likely to develop TB, it is estimated that TB is responsible for 40% of the 3 million AIDS deaths in Africa each year.

These deaths are unconscionable because both Malaria and TB can be prevented. Mosquitoes spread malaria, so simply using insecticides and bednets can do much to stop the spread of the disease. But, less than 5% of African children sleep under bednets treated with insecticides.

Why? Because a bednet that costs about \$5 is simply too expensive.

Drugs that treat malaria have also had some success, though a growing resistance to cheaper drugs that have typically been in use are escalating the price of treating malaria.

While there are other methods that have had some success, for many African countries and their peoples, they are not affordable without our help.

\$2 billion a year over the next 6 years is what is needed to decrease the prevalence of malaria to half by 2010. It is a pledge the world must begin to honor and there is no reason that the US should not be a leader in these efforts.

Now, because TB is a highly contagious airborne disease, it has proved to be an extreme danger to those with weakened immune systems, such as impoverished children and persons infected with AIDS. An average person with TB is projected to infect 10–15 people per year.

But again, there are solutions. Drug programs such as DOTS, where family and others play a role in ensuring that patients complete their TB rates have had a success rate of around 80% in poor regions in the world.

In the words of Nelson Mandela, “we can’t fight AIDS unless we do much more to fight TB as well.” Fighting TB must be as much of a priority in Africa as fighting AIDS.

If we are to see Africa truly benefit from AGOA and other development efforts we must do what we can to stop the negative impact of disease on Africa’s human resources.

Both Malaria and TB result in lost life and lost productivity due to illness and premature death, but malaria also hampers children’s schooling and social development through both absenteeism and permanent neurological and other damage associated with severe episodes of the disease.

There are solutions to fighting both Malaria and TB and helping Africa to become the healthy partner we need to implement security reforms that will aid in the fight against terror, become a viable trade partner, and establish strong democracies.

If we are truly serious about helping Africa to reach those goals, we must help to ensure that Africa has a healthy populace as well. Working to eradicate malaria and TB are just the beginning.

Thank you.

PREPARED STATEMENT OF DR. PAUL NUNN, WORLD HEALTH ORGANIZATION

SYNOPSIS OF GLOBAL TB CONTROL

Introduction

About 9 million people around the world developed tuberculosis (TB) for the first time in 2002, of whom nearly 2 million died.^{1,2} Globally, TB is currently responsible for more years of healthy life lost (2.5% of all Disability Adjusted Life Years, DALYs) than any other infectious disease, except for AIDS and malaria.³ The scale of the global TB epidemic in numbers represents an enormous scale in human suffering, pain and grief. The stigma attached to TB has psychological and social consequences. TB is also costly. The direct monetary costs of diagnosis and treatment are borne by health services, and by patients and their families. Added to these are the indirect costs of lost income and production, incurred when TB patients are too sick to work, and when young adults (often parents and householders) die prematurely.⁴ A problem of such magnitude demands an urgent and effective response. This paper briefly reviews the current state of the global TB epidemic and of TB control efforts, the constraints to progress, and future directions for faster progress in global TB control.

The current status of the global TB epidemic

There were 8.8 million new cases of TB in 2002, of which 3.9 million had sputum smear-positive pulmonary TB (the most infectious type of TB). Between 1995 and 2002 the global incidence rate of TB (per capita) was growing at approximately 1.1% per year, and the number of cases at 2.4% per year. The growth in case notifications has been much faster in African countries with high HIV prevalence, and in eastern Europe (mainly the former Soviet Union). In other regions of the world, the case notification rate has been roughly stable or in decline.

Sub-Saharan Africa

The incidence rate of TB in the WHO African region is growing at approximately 4%/year, and at 6%/year in eastern and southern Africa, faster than on any other continent, and considerably faster than the 1.2%/year global increase.¹ In several African countries, including those with well-organized control programmes, annual TB case notification rates have risen more than fivefold since the mid 1980s, reaching more than 400 cases per 100,000 population.¹ HIV infection is now the most important single predictor of TB incidence across the African continent.

The former Soviet Union

The 10%/year increase in TB incidence rate in the former Soviet Union is assumed to be a consequence of increased breakdown following infection to disease. This largely results from the overall decline in health status of the population and in public health infrastructure over the past fifteen years. The full impact of the spread of HIV infection on the TB epidemic remains to be seen.

The current status of global TB control efforts

While research holds out the prospect in the mid- to long-term of improved or new drugs, diagnostics and vaccines which could dramatically decrease the global TB burden, the current basis of global TB control is the interruption of disease transmission by identifying infectious cases as rapidly as possible and curing them with anti-TB treatment.⁵ The five elements of the DOTS strategy represent the policy package for delivering the essential basics of TB case-finding and cure: a) sustained government commitment; b) diagnosis based on quality-assured sputum-smear microscopy mainly among symptomatic patients presenting to health services; c) standardised short-course chemotherapy for all cases of TB, under proper case-management conditions including direct observation of treatment; d) uninterrupted supply of quality-assured drugs; e) a standard recording and reporting system enabling programme monitoring by systematic assessment of treatment outcomes of all patients registered.

The global targets set by the World Health Assembly are to detect at least 70% of all estimated infectious cases and treat successfully at least 85% by 2005.⁶ As countries implement the DOTS strategy fully and achieve these targets for case detection and treatment success, the global burden of TB cases and deaths will diminish. Beyond 2005, the focus of international health efforts will be on achieving the 2015 Millennium Development Goals, including starting to decrease the global incidence of TB.

The number of countries implementing the DOTS strategy increased by 25 during 2002, bringing the total to 180 (out of 210). National TB Programmes (NTP) reported that, by the end of 2002, 69% of the world's population lived in countries,

or parts of countries, covered by DOTS. DOTS programmes notified 3.0 million new TB cases, of whom 1.4 million had sputum smear-positive pulmonary TB. A total of 13.3 million TB patients, and 6.8 million patients with sputum smear-positive pulmonary TB, were treated in DOTS programmes between 1995 and 2002. The 1.4 million smear-positive cases notified by DOTS programmes in 2002 represent 37% of the estimated incidence, just over half way to the 70% target.

Treatment success under DOTS for the 2001 cohort (the most recent cohort for which treatment outcome results are available) was 82% on average. As in previous years, treatment success was substantially below average in the WHO African Region (71%) and in eastern Europe (70%) (attributable, in part, to the consequences of HIV co-infection and drug resistance respectively).

Thus regarding progress in 2002 towards the 2005 targets, the 82% global treatment success is close to the 85% target (although special efforts are necessary to improve treatment success in the sub-Saharan Africa and in the former Soviet Union), but the 37% case detection rate is only half the 70% target.

Constraints to progress in global TB control

The managers of the National TB Programmes (NTPs) of the 22 highest-burden countries (HBCs) have identified the main constraints to more rapid progress in global TB control. The six most common constraints were the following: 1) lack of qualified staff; 2) poor monitoring and evaluation of NTP performance; 3) inadequate health infrastructure; 4) weak laboratory services; 5) the failure of DOTS programmes to engage the full range of health care providers (including all public providers, NGOs and private practitioners); and 6) inadequate provision of funding and capacity-building in countries with decentralised health systems.

Remedies to overcome these constraints include: 1) the development of staffing plans for TB control that are consistent with plans to strengthen the health workforce in general; 2) strengthened management and technical capacity of NTPs; 3) increased investment in health infrastructure improvements; 4) increased investment specifically in laboratory services; 5) schemes to involve the full range of health care providers in delivering TB care (including mobilisation of local NGOs and community volunteers for community care, e.g. through religious networks); and 6) the provision of adequate funding and the building of local capacity in countries with decentralized health systems. Collaboration with other constituencies within the health sector and intersectoral collaboration beyond the traditional TB constituency will be critical in overcoming constraints that lie beyond the full control of NTPs.

Multidrug-resistant tuberculosis (MDR-TB) is a serious threat to global TB control, arising wherever there has been, or is currently, inadequate application of anti-TB chemotherapy. An assessment of the number and distribution of drug-resistant TB cases is important for planning TB control, because the treatment of resistant cases is more costly and more complex where second-line drugs are used, with more frequent failures and deaths. Surveys in the mid-late 1990s identified a high prevalence of MDR-TB among new TB cases in specific regions of the world, e.g. Estonia (14%), Latvia (9%), the Oblasts of Ivanovo (9%) and Tomsk (6.5%) in Russia, and the provinces of Henan (11%) and Zhejiang (4.5%) in China.

Despite considerable increases in the funding made available for TB control by the governments of the high TB incidence countries and of the donor countries, many countries still face a shortfall in the funding needed to reach the global targets. Statements of political commitment by government leaders must be matched by concrete support in terms of increased funding. The Global Fund to fight HIV, TB and malaria is likely to make a large contribution to supporting TB control if able to make more rapid disbursements. As a result of substantial increase in funding in countries there is a massive request from countries for technical support in order to assist in planning, building capacity to implement activities and monitoring progress. However there has been no increase in funding the technical assistance and Stop Tb partners are not able to respond to all demands.

Future directions for faster progress in global TB control

The particular problems which HIV and drug-resistance pose for TB control require particular solutions. Sub-Saharan Africa specifically requires increased support for implementation of the strategy of expanded scope to counter HIV-fuelled TB, consisting of measures directly against TB (full implementation of the DOTS strategy with intensified case-finding and TB preventive treatment) and measures against HIV (and therefore indirectly against TB), including prevention of HIV transmission and provision of ARV treatment. Full implementation of the DOTS strategy and full implementation of measures for HIV prevention and care requires enhanced collaboration between tuberculosis and HIV/AIDS programmes. Progress in preventing the emergence of MDR-TB depends on full implementation of the

DOTS strategy globally with effective NTP performance and high treatment success rates. Progress in countering the spread of MDR-TB depends on the rapid identification of patients with MDR-TB and their effective treatment with second-line drugs.

Faster progress towards the global TB control targets depends on action at different levels. At the global level, progress depends on raising the profile of TB on political and development agendas, mobilising increased political commitment and funding, and strengthening and diversifying the Global Partnership to Stop TB. At the level of the high TB incidence countries, progress depends on engaging the full range of health providers, and undertaking the necessary regulatory and legislative reform. With their key role as health care providers to often large sections of the population, the mission hospitals and clinics are well placed to make a vital contribution to increased access to TB care delivered through the DOTS strategy. Promotion of community action is necessary to contribute to tuberculosis patient care and to voice demand for the DOTS strategy.

What are the resources required to control TB in high burden countries (HBC)?

The resources required to implement basic DOTS strategy in 22 HBCs, if global targets are to be reached in 2005, are about 1 billion a year of which 800 million are met by national budgets, loans and grants leaving a gap of 200 million. However this figure does not take into account the needs for TB/HIV joint activities that can be estimated at 300 million a year and treatment of MDR-TB which has not yet been estimated but will be higher than the others.

The resources required for technical assistance to countries and monitoring have been estimated at approximately 50 millions a year, of which around 25 million are available in 2004. Scaling up activities for MDR-TB will require additional support that is currently being estimated.

Key documents

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Footnotes

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PREPARED STATEMENT OF FIONA KOBUSINGYE-BOYNES

Good afternoon, distinguished members of the subcommittee and guests. I thank the organizers of this historic meeting for allowing me to tell my story today. In a very real sense, it is the story of the people of Africa.

I come from Uganda, which is in the middle of the African Continent, at the beginning of the Nile River. Sir Winston Churchill called Uganda the “pearl of Africa”

when he first visited my country at the beginning of the 20th century, and it has been known that way ever since.

As a little girl, I already suffered from malaria, as did my parents, sisters and brothers. Two of my sisters and my son died from the disease. Just last year, I lost my nephew, an active young boy 14 years old, to malaria—and another died just months ago, in late 2003, as I myself lay stricken with malaria in a different hospital. He was a brilliant and gifted 16 year-old, and the pride of our family, and we miss him terribly.

My situation is not unusual in Africa, as malaria is the most common and most deadly disease in large parts of our great continent. Millions and millions of people die from it, often in combination with AIDS, dysentery, typhus and other diseases.

The root causes are known. Mosquitoes are the vectors that transmit malaria. Medicines that formerly protected us, and saved people, have lost their potency. Now, there is a lack of new effective medicines, and what exist are very expensive and hard to get. Many people simply can't afford the medicines, or else they would have no money left for food or other things.

There likewise is no powerful vaccine against malaria, and many experts say there will never be one, because no one ever seems to become immune, even after getting malaria over and over.

Malaria is a great enemy of development, as it makes young and energetic people sick and weak—and even kills them. It strikes quickly, leaving people unable to work or go to school or take care of their families, within days after they get infected. Millions of others must stop working or leave school, to take care of sick people in their families.

Fighting malaria is not only a humanitarian need. It is also economically important, both for the developing countries and for the USA and other countries. Something most people don't realize is that the same African countries that are most infected by malaria are also the poorest ones on our continent. That is because the disease makes so many millions of people in those countries too sick and weak to earn a living or cultivate their fields.

I myself have suffered high fevers for days, vomited until I thought I had no stomach left. It has left me dehydrated, thirsty and weak, and sometimes I could not even tell day from night. It is a terrible disease. You just can't imagine.

What can be done?

People in the north, in other words USA and Europe, always think of AIDS when they think of troubled Africa. They should remember that malaria is even more important for many tropical countries. It affects more people. It kills them more quickly. And it makes them sicker than AIDS does, until that disease is very advanced in their bodies.

The first thing that should be done is to support more medical research and the development of new medicines to help the people who are already sick with malaria.

Secondly, we must try to kill the mosquitoes by spraying our homes. I know many well-meaning people say DDT is not good for the environment. But it is still the best means to kill the mosquito that causes malaria. It also keeps them out of our houses, because the mosquitoes do not seem to like the smell of DDT. And the way we use it won't hurt animals.

Nothing works as well as DDT, and it is the only pesticide that mosquitoes are not resistant to. We only need to spray tiny amounts on our houses one or two times a year, and we are protected. Without DDT, the mosquitoes are everywhere, and they come and bite us whenever they want.

If people in Africa are to be saved, we must stop the primary cause, the mosquito that carries malaria. Of course, we are concerned about our environment. We live in it. But should we not be concerned about our loved ones, our people, first?

Just as important, we must help develop sanitation systems and dry out or treat puddles and swamps that are breeding grounds for mosquitoes. We must educate our people about malaria. We can let them know that it is preventable, and that they must begin to take more responsibility to eradicate this terrible disease from their families. But we must have pesticides, too. We must have DDT, or we and our children will continue to die.

In Uganda, we are developing a project called "Kogere." We take local fibers, make them into traditionally crafted mats, and convert the mats into high quality ladies' handbags. We are beginning to export the bags to the United States, and even the Smithsonian Institution is interested in buying them for their shops.

But we are not interested in just selling handbags. We want to create income that will change the lives of families and save lives in Uganda. Many of the women we have organized have few options to earn cash. The income that is generated from the sale of these bags helps women, especially single unemployed women who are

supporting their families, to be able to buy the drugs that are needed to ease suffering from malaria and, yes, sometimes from AIDS, too.

I am not a medical doctor or a politician. I am just an African woman with a wish. That wish is that we join hands together to—

- educate our people about what they can do personally to combat malaria;
- influence our leaders and politicians to make the right decisions about the most effective means to fight malaria, like the use of DDT, and finally
- find and join with friends who have the financial resources, the money, to start effective campaigns that can finally end this disease that is wiping out the future of Africa—our precious children.

Ladies and Gentlemen, again thank you for this opportunity.

